IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation, *et al*. Defendants.	)	Civil Action No. 04-12457 PBS

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S OPPOSITION TO DEPUY MITEK'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50 AND MOTION FOR A NEW TRIAL

Dated: October 18, 2007

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I. INTRODUCTION

Defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") submit this opposition to DePuy Mitek, Inc.'s ("DePuy Mitek's") renewed motion for judgment as a matter of law under FED. R. CIV. P. 50 and motion for a new trial ("Mitek Mem."). DePuy Mitek's motion should be denied on several grounds. First, DePuy Mitek purports to renew its original motion for judgment as a matter of law made under Rule 50(a); however, as described below, DePuy Mitek's Rule 50(a) motion at trial was improper because it failed to state any grounds and made no reference to the law or the facts, and thus, can not be renewed under Rule 50(b). Second, DePuy Mitek's motion for a new trial under Rule 59 was improper because it failed to state any grounds on which it was based, as required by the Federal Rules; and it cannot be cured by DePuy Mitek's later-filed memorandum.

Should the Court reach the merits of DePuy Mitek's motion, there are a multitude of reasons why it should be denied. For example, DePuy Mitek argues, as a matter of law, that FiberWire's coating does not materially affect the basic and novel properties of the '446 patent merely because the '446 patent mentions that a coating can be used on the disclosed suture. As this Court has already explained over and over again, both at the summary judgment phase and at trial, DePuy Mitek is wrong. The most that can be said about the '446 patent is what the Court has repeatedly said: it "says all things to all people," and "[coating] can help; it can hurt." In such circumstances, mere reference to the patent cannot decide the issue as a matter of law.

DePuy Mitek also asserts that it is entitled to judgment as a matter of law because there was no legally sufficient basis for the jury's verdict of non-infringement because FiberWire's coating is merely a surface coating that does not permeate the braid. In its Memorandum, however, DePuy Mitek repeatedly misrepresents and/or simply ignores the

Court's claim construction, and then asserts that the evidence it presented at trial proves that FiberWire's coating does not materially affect its version of the claim construction.

As described below, Defendants presented overwhelming evidence at trial that FiberWire's coating materially affects the basic and novel properties of the invention -- *i.e.*, the coating materially affects FiberWire's handleability and pliability properties. Once again, this Court already recognized -- correctly -- that such evidence would be sufficient to support Defendants' position. Ex. 1 at 24:18-25:1. That is the short and dispositive answer to DePuy Mitek's motion.[1]

II. DEPUY MITEK'S RULE 50(a) MOTION WAS IMPROPER, AND THEREFORE, CANNOT NOW BE RENEWED UNDER RULE 50(b)

To properly move for judgment as a matter of law, a party "must specify the judgment sought and the law and facts that entitle the movant to the judgment" before the case is submitted to the jury. FED. R. CIV. P. 50(a)(2). "A general reference to a count, which is the most that [movant] can be said to have provided, is insufficient to meet the rule's requirements." *W.S. Molnar Co. v. IKG Industries*, 82 F.3d 434, 1996 WL 128262 at *1 (Fed. Cir. 1996) (unpublished), Ex. 2. *See also American National Fire Ins. Co. v. Mirasco, Inc.*, 451 F. Supp. 2d 576, 580-883 (S.D.N.Y. 2006). Further, "the grounds supporting [a Rule 50(a)] motion must be specifically articulated, and may include explicit references to material and arguments previously supplied to the court." *Id.* at 581. *See also* FED. R. CIV. P. 50 advisory committee's note (1991).

At the close of Defendants' case at trial, counsel for DePuy Mitek stated "[y]our Honor, they have a declaratory judgment counterclaim for noninfringement, and we're moving as a matter of law on that counterclaim." Ex. 3 at 804:25-805:2. DePuy Mitek stated absolutely no grounds for its Rule 50(a) motion, nor did DePuy Mitek include explicit references to

[1] Even if DePuy Mitek's perversion of the claim construction were correct, its motion should still be denied because there was sufficient evidence that the FiberWire coating does permeate the braid.

materials and arguments previously supplied to the court to remedy these deficiencies. Thus, DePuy Mitek's purported Rule 50(a) motion was totally inadequate.

"A post-trial motion for judgment can be granted only on grounds advanced in the pre-verdict motion." FED. R. CIV. P. 50 advisory committee's note (1991) (citing *Kutner Vuick, Inc. v. American Motors Corp.*, 848 F.2d 614 (3rd Cir. 1989)). *See also American National Fire Ins. Co.*, 451 F. Supp. 2d at 581. Since DePuy Mitek failed to articulate grounds supporting its Rule 50(a) motion; it cannot now cure that deficiency by articulating grounds in a post-verdict memorandum. Thus, as DePuy Mitek's Rule 50(a) motion was insufficient, DePuy Mitek cannot renew that motion pursuant to Rule 50(b).

III. DEPUY MITEK'S MOTION FOR A NEW TRIAL UNDER RULE 59 IS IMPROPER AND CANNOT BE CURED BY ITS MEMORANDUM

DePuy Mitek's first and only motion for a new trial under Rule 59 was filed on August 28, 2007. That motion, however, failed to state *any* grounds on which it was based; a failure that is fatal to DePuy Mitek. Rule 7(b) requires that motions "shall state with particularity the grounds therefore." FED. R. CIV. P. 7(b). DePuy Mitek simply failed to file a proper motion within the time limit prescribed by FED. R. CIV. P. 59(b),[2]

Moreover, DePuy Mitek's memorandum in support of its motion under Rule 59, which was filed after the ten-day deadline, is insufficient to cure this deficiency. *Riley v. Northwestern Bell Telephone Co.*, 1 F.2d 724, 726-727 (8th Cir. 1993) (stating that "overlooking the defect of this document would only serve to whittle away at the rules and ultimately render them meaningless and unenforceable"); *Hinz v. Neuroscience, Inc.*, No. 04-CV-0142(PJS/RLE)

[2] While DePuy Mitek obtained an extension to file a memorandum in support of its motion, DePuy Mitek did not request, nor could it have requested, an extension for filing its motion. *Vargas v. Gonzalez*, 975 F.2d 916, 917 (1st Cir. 1992) ("the ten-day deadline is mandatory, Fed. R. Civ. P. 6(b), and it is well established that the district court has no power or discretion to modify it.").

Slip Copy, 2007 WL 1576116 at *3 (D. Minn. May 31, 2007). Ex. 4. Thus, since DePuy Mitek's Rule 59 motion was improper, it should be denied.

IV. STANDARDS FOR GRANTING MOTIONS UNDER FED. R. CIV. P. 50 AND 59

Judgment as a Matter of Law is appropriate only where "there is no legally sufficient evidentiary basis for a reasonable jury to find for [a] party on [an] issue." FED. R. CIV. P. 50(a)(1). "Courts may only grant a judgment contravening a jury's determination when the evidence points so strongly and overwhelmingly in favor of the moving party that no reasonable jury could have returned a verdict adverse to that party." *Marcano Rivera v. Turabo Medical Center Partnership*, 415 F.3d 162, 167 (1st Cir. 2005) (quoting *Rivera Castillo v. Autokirey, Inc.*, 379 F.3d 4, 9 (1st Cir. 2004)). In entertaining a motion for judgment as a matter of law, "the court must draw all reasonable inferences in favor of the nonmoving party, and it must not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 150 (2000). While "the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury is not required to believe." *Id.* at 151.

"A verdict may be set aside and new trial ordered [pursuant to Rule 59] when the verdict is against the clear weight of the evidence, or is based upon evidence which is false, or will result in a clear miscarriage of justice." *Ahern v. Scholz*, 85 F.3d 774, 780 (1st Cir. 1996) (citation omitted). While the court has discretion, it "must be exercised with due regard to the rights of both parties to have questions which are fairly open resolved finally by the jury at a single trial." *Id.* (citation omitted). The court "cannot displace a jury's verdict merely because [it] disagrees with it or would have found otherwise in a bench trial." *Id.* (citation omitted). Indeed, "[t]he mere fact that a contrary verdict may have been equally -- or even more easily -- supportable furnishes no cognizable ground for granting a new trial." *Id.* (citation omitted)

V. DEPUY MITEK IS NOT ENTITLED TO JUDGMENT AS A MATTER OF LAW BASED ON THE DISCLOSURE OF THE '446 PATENT

In what amounts to nothing more than a regurgitation of its failed summary judgment motion, DePuy Mitek wrongly asserts that, as a matter of law, coating cannot materially affect the basic and novel properties of the invention because the '446 patent states that a coating may be applied to the disclosed suture. Mitek Mem. at 1, 11-12; Ex. 5 at 7-9. DePuy Mitek was legally wrong when it first made this argument and it is legally wrong today.

Citing *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234 (Fed. Cir. 2003), the Court noted in its Memorandum and Order dated January 31, 2007, "where the specification and/or prosecution history *directly speaks to and conclusively answers the question of what constitutes a material affect*, the issue may be resolved as a question of law." Ex. 6 at 14 (emphasis added). The *only* way DePuy Mitek can assert that *AK Steel* supports its motion is by ignoring this very important language.

For example, DePuy Mitek asserts that it is entitled to judgment as a matter of law because "the '446 patent expressly teaches one of ordinary skill in the art that surface coatings may optionally be applied to the braided sutures claimed in the patent, in other words they are part of the invention." Mitek Mem. at 10. But DePuy Mitek conveniently forgets the well-established law that the assertion in a patent that an ingredient can be added does *not* establish the added ingredient cannot have a material effect on the basic and novel properties of the invention. *Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1319-20 (Fed. Cir. 2006); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239 (Fed Cir. 2001); *American Machine & Foundry Co. v. Liggett & Myers Tobacco Co.*, 172 F. Supp. 12, 19 (D. N.J. 1959).[3]

[3] DePuy Mitek also makes the facile argument that if applying a coating to FiberWire "removes [it] from the scope of the Hunter 446 Patent, then the patent is not worth the paper it is written on" which would be "an absurd result." Mitek Mem. at 4. The short answer is "so what;" even if DePuy Mitek's assertion were true, court's simply decide patent claims as they are written. Moreover, DePuy Mitek's protestations are wrong. DePuy Mitek itself put in evidence that not all sutures are coated (Ex. 3 at 155:5-13; 406:1-4), and more importantly, DePuy Mitek

Rather, as *AK Steel* states, and as this Court correctly observed, the issue can be decided as a matter of law if the 446 patent "directly speak[s] to and conclusively answer[s] the question of *what constitutes a material effect.*"[4] On this relevant question, the Court already explained that the '446 patent does not conclusively answer the *AK Steel* question. As the Court stated, the '446 patent "says all things to all people," and that "[coating] can help; it can hurt." Ex. 1 at 12:8-11.

Without question, there is an overabundance of evidence that the use of coating (including what DePuy Mitek characterizes as "surface coating")[5] does materially affect the basic and novel characteristics of the invention. For example, the '446 patent states that there are "deficiencies which plague conventionally coated sutures" and that it is best to eliminate and avoid a coating. Ex. 7 at col. 2, ll. 11-13; col. 6, ll. 15-16. Moreover, the '446 patent also

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knows that the effect of the coating must be material; something that is not automatically true just because there is a coating.

Further, in the facts of this case, DePuy Mitek's argument is mere makeweight. DePuy Mitek conveniently fails to mention that the claims as originally filed with the Patent Office did *not* contain the "consisting essentially of" transitional phrase. Rather, the transitional phrase in the original claims was "comprising." For a "comprising" claim, it is no defense that the accused product has additional unlisted materials. *Free Motion Fitness, Inc. v. Cybex Intern, Inc.*, 423 F.3d 1343, 1353 (Fed. Cir. 2005). Accordingly, it makes perfect sense, as the application was originally filed, that the patent would state that coating could be used to further improve handleability. But once the transitional phrase "consisting essentially of" was added to the claim, which in turn narrowed the claim as a matter of law, DePuy Mitek's rationale falls apart. Since the transitional phrase was amended to "consisting essentially of," the use of a coating which is *unlisted* in the claims *does* avoid infringement if that coating materially affects the basic and novel characteristics of the invention. As described herein, there is no question that it does.

[4] DePuy Mitek asserts that "the Hunter 446 Patent 'directly speaks' about surface coating." Mitek Mem. at 12. It simply ignores the *second* requirement -- that the patent "conclusively answer the question of what constitutes a material effect."

[5] DePuy Mitek acknowledges that the coating added to FiberWire is the same as the conventional coating described in the '446 patent. Mitek Mem. at 12. Dr. Steckel also acknowledged at trial that the "conventional coatings," described in the '446 patent are "the same conventional standard coatings that everyone" in the industry, "including Arthrex and Johnson & Johnson" uses. Ex. 3 at 175:13-20.

discloses that coating improves suture handleability and knot tiedown (Ex. 7 at col. 6, ll. 5-8), itself an *admission* that coating materially affects the basic and novel properties of the invention.

Indeed, the goal of the '446 patent was to design a braid that *did not require a coating*. The '446 patent proudly proclaims that the benefits of the invention were "due *entirely* to the mechanical interlocking or weaving of the individual yarns." Ex. 7 at col. 2, ll. 55-58. [Emphasis added]. In other words, it achieves the goals *without* coating. It comes as no surprise that Dr. Steckel's testimony regarding his development of the invention is entirely consistent. He testified that *none* of the sample braids that he tested, the results of which are described in the '446 patent, had a coating on them. Ex. 3 at 176:10-177:8. Dr. Steckel also wrote in his lab notebook that "the composite [braid] also ranked better than the silk and Ethibond in knot tiedown *even without a coating*." Ex. 8 at DMI2666. [Emphasis added]. Dr. Steckel confirmed that these were his findings and that "on this one particular embodiment, *you may not want to add a coating*." Ex. 3 at 178:4-12. [Emphasis added].[6] For all these reasons, the Court should, once again, reject DePuy Mitek's oft-repeated, but always-incorrect, argument.

VI. THE JURY HAD A LEGALLY SUFFICIENT EVIDENTIARY BASIS FOR ITS VERDICT OF NON-INFRINGEMENT

The Court construed the basic and novel properties of the '446 patent invention as follows:

> (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture.

Ex. 6 at 18-19. The jury was instructed that these are the basic and novel properties of the '446 patent. Ex. 9 at 14:2-10; Ex. 3 at 890:22-891:10. Defendants presented *overwhelming* evidence

[6] If anything, Defendants submit that the evidence is so overwhelming that, as a matter of law, the Court should find that coating *does* affect the basic and novel characteristics.

at trial that the coating added to FiberWire materially affects these basic and novel properties of the '446 patent.[7] Specifically, Defendants showed unequivocally, that the FiberWire coating materially and dramatically affects both the handleability and pliability of the suture. And, Defendants also showed that the coating materially, and adversely, affects a physical property -- knot security -- of the suture; yet another reason to uphold the jury's finding.

For example, with respect to coating's effect on FiberWire's handleability and pliability:

- Ms. Ashley Willobee, Arthrex's director of research, conducted a knot rundown test showing that two-and-one-half-times more force was required to move a half-hitch knot down a line of uncoated suture as compared with a line of coated suture. Ex. 10; Ex. 3 at 511:6-10; 515:19-24.
- Dr. Stephen Burkhart testified that it was understood from the very beginning of the FiberWire development that it would have a coating. He explained that since FiberWire is a braided suture, it is bumpy and has a lot of friction and the coating smoothes out the bumps and reduces the coefficient of friction. Ex. 3 at 450:14-451:6; 461:18-462:2.[8]
- Dr. Norman Gitis, president of CETR, tested several suture handleability parameters and explained that the difference between the coated and uncoated FiberWire was 60% for the pliability test, 81% for the knot run-down test,

[7] An effect is material if it is of importance or of consequence to a person of ordinary skill in the art. Ex. 9 at 15:22-16:6; Ex. 3 at 892:22-893:6

[8] DePuy Mitek points to Dr. Burkhart's testimony that the original idea for FiberWire was a "killer idea" and tries to create the impression that Dr. Burkhart was commenting on a prototype without coating. Mitek Mem. at 14-15. But, Dr Burkhart explained that his "killer idea" comment in no way meant the suture did not have to be coated. To the contrary, as mentioned above, Dr. Burkhart explained that it was understood from the very beginning that FiberWire would require a coating so that it has a low enough coefficient of friction so you can tie a knot. Ex. 3 at 460:23-462:2.

77% for the friction test, 55% for the chatter test, 30% for the static tissue drag test and 56% for the dynamic tissue drag test. He also explained that these differences were statistically meaningful and statistically substantial. Ex. 11; Ex. 3 at 615:4-619:15; 625:22-629:12; 629:13-631:11; 631:16-634:13; 635:3-636:24; 637:3-638:18; 642:7-644:4.[9]

- Dr. Robert Burks evaluated samples of coated and uncoated FiberWire for knot tie-down both in connection with his expert report and also in connection with his deposition. Even though Dr. Burks was never told which samples were coated and which were uncoated, *every time* he was able to distinguish the coated FiberWire from the uncoated FiberWire. Ex. 12 at ¶¶ 12-13; Ex. 3 at 427:21-428:10.
- Mr. Lawson Lyon, managing director of Pearsalls, Ltd. ("Pearsalls"), testified that he believed FiberWire required a coating "because a braid without a coating does not give you good knot run-down and the surgeons would not be happy to have a suture like that." Ex. 3 at 549:12-15. Mr. Lyon also testified that Arthrex's FiberWire patent describes why coating is added to FiberWire -- *i.e.*, "to fill in voids and provide optimum run-down." Ex. 13 at col. 2, l. 48; Ex. 3 at 552:15-19.
- Dr. Debi Mukherjee testified that in his opinion, the silicone coating added to FiberWire materially affects the basic and novel properties of the invention. Ex. 3 at 705:14-22. His opinion was based on his decades of experience

[9] Notably, Dr. Gitis testified that CETR sold the same testing machine used to conduct his tests on FiberWire suture to Ethicon, Inc., another Johnson & Johnson company, and the assignee listed on the face of the '446 patent. Ex. 3 at 608:7-12. Dr. Gitis also performed similar suture tests for both Ethicon and U.S. Surgical (another very large suture manufacturer) and that the pliability test he conducted on FiberWire was the same pliability test he performed in the past for Ethicon, Inc. Ex. 3 at 609:16-19; 616:15-24.

working with sutures, the suture patent literature, including an Ethicon patent, Ethicon documents, the testimony of DePuy Mitek and Ethicon witnesses, Arthrex documents, and tests conducted by Dr. Gitis and Ms. Willobee. Ex. 3 at 705:14-22; 706:8-707:1; 707:8-17; 708:9-24; 709:4-10; 709:17-712:20; 714:23-715:5; 718:9-23; 719:16-720:6; 723:1-9; 726:1-23; 728:14-18.

And with respect to FiberWire's knot security (*i.e.*, one of a suture's physical properties, according to the '446 patent),[10] Dr. Gitis's tests revealed that coating has a significant detrimental effect. In fact, Dr. Gitis's tests revealed that the knot security of the coated FiberWire was 50% worse than that of the uncoated FiberWire. Ex. 11; Ex. 3 at 639:4-641:7.

At trial, DePuy Mitek's principal contention was that the FiberWire coating had no material impact on suture handleability or pliability, and more specifically, had nothing to do with "smoothing out the braid." Recognizing, as it must, that the jury could (and did) rightfully reject its contentions, DePuy Mitek abandons these trial arguments and now argues that none of this overwhelming evidence matters. According to DePuy Mitek now, enhancing handleability and pliability has "nothing to do" with the basic and novel properties of the invention because the FiberWire coating does not permeate the braid. Mitek Mem. at 18. DePuy Mitek is both legally and factually wrong.

DePuy Mitek asserts that the basic and novel properties "have to do with the mechanical blending of dissimilar materials to reap the benefits of each material." Mitek Mem. at 18. But, this language *appears nowhere in the Court's claim construction*. More importantly, DePuy Mitek's assertion simply *ignores* the last portion of the basic and novel properties: "(4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture." As the Court made clear, and as DePuy Mitek itself

[10] Ex. 7 at col. 2, ll. 31-37; 62-66.

inadvertently seems to recognize, it is the handleability and pliability *of the suture braid itself* that needs to be materially affected. Ex. 6 at 16-18; Mitek Mem. at 1, 7. Of course, this comes as no surprise as the '446 patent makes it abundantly clear that the basic and novel characteristics involve improvements to the *suture braid* itself. Ex. 7 col. 2, ll. 32-37.

DePuy Mitek's argument here is nothing more than a regurgitation of the ill-conceived argument already-rejected by this Court during summary judgment, where, as here, DePuy Mitek tried to ignore the claim construction. Discussing, at the summary judgment hearing, a declaration prepared by Dr. Brookstein, this Court previously rejected DePuy Mitek's attempt to gloss over relevant portions of the Court's claim construction as if they were not there. DePuy Mitek asserted:

> And your Honor's construction, which we contend is correct, is that whatever the additional element is, it cannot sacrifice the physical properties of the constituent elements of the suture, and that's what Dr. Brookstein says in his declaration.

Ex. 1 at 24:6-10.

In response to this assertion, the Court correctly noted:

> I think Dr. Brookstein's declaration is certainly relevant. It's just not a bingo for you *because he doesn't actually check to see whether it improves the pliability and handleability*.

Ex. 1 at 24:11-14. [Emphasis added].

DePuy Mitek responded as follows:

> With all due respect, your Honor, I don't know that that is really the issue under this construction of basic and novel characteristics.

Ex. 1 at 24:15-17.

The Court responded:

> *It's both. It's got to improve the handleability and pliability without impeding or sacrificing the physical properties.* So he tells you it isn't sacrificing anything, but if it also improved handleability, wouldn't that take you out of infringement under a 'consisting essentially of'?

Ex. 1 at 24:18-23. [Emphasis added].

As the Court correctly stated at the summary judgment hearing, and as DePuy Mitek continues to disregard, if the FiberWire coating materially affects FiberWire's handleability and/or pliability, there is no infringement. As described above, Defendants presented overwhelming evidence that FiberWire's coating *does* materially improve both its handleability and pliability.[11]

But even if DePuy Mitek's attempt to rewrite the claim construction were valid -- and it certainly is not -- DePuy Mitek's motion must still be denied because both sides presented evidence as to whether the coating permeates the braid. The jury, of course, was free to reject DePuy Mitek's evidence and accept Defendants' evidence.

For example, Dr. Mukherjee testified that based on his review of Dr. Brookstein's scanning electron micrographs ("SEMs") of FiberWire, it appeared to him that the coating does penetrate into the braid. Ex. 3 at 742:3-8.

Dr. Mukherjee also explained that there is a phenomenon which draws coating from outside of the braid to within the braid known as the "wicking" effect. Based on FiberWire's braided construction, it was Dr. Mukherjee's opinion that FiberWire's coating penetrates into the

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[11] DePuy Mitek also asserts what it knows to be a legally-incorrect argument -- *i.e.*, that coating cannot have a material effect on the basic and novel properties of the '446 patent since the coating "enhances," rather than detracts from, the pliability of the suture. Mitek Mem. at 17. This assertion is surprising because DePuy Mitek already admitted at the *Markman* hearing that an added ingredient can materially affect the basic and novel properties even if it materially *improves* rather than materially *detracts*. Ex. 14 at 16:16-17:1. DePuy Mitek had no choice but to acknowledge this, because it is the well-known law of "consisting essentially of" claims. *See, e.g., Kim v. Conagra Foods, Inc.*, 465 F.3d 1312, 1319-20 (Fed. Cir. 2006); *AFG Indus., Inc.*, 239 F.3d at 1246; *Bayer A.G. v. Sony Electronics, Inc.*, 228 F. Supp.2d 332, 346-47 (D. Del. 2002); *Binney & Smith v. Rose Art Indus., Inc.*, 1995 U.S. Dist. LEXIS 2602 at *30 (N.D. Ill. 1995) (Ex. 15); *American Machine*, 172 F.Supp. 12, 19 (D. N.J. 1959).

For the same reasons, DePuy Mitek's reference to Dr. Brookstein's "card trick" is irrelevant. Mitek Mem. at 16. Dr. Brookstein's misleading and prejudicial card trick demonstration was designed to mislead the jury into believing the only way FiberWire's coating can materially affect the basic and novel properties of the invention is if it were to somehow get into the braid *and* detract from its pliability. Ex. 3 at 274:11-277:16. That is not the law.

braid through this wicking effect. Ex. 3 at 742:15-743:1. Moreover, the fact that FiberWire's pliability is so dramatically improved after it is coated, as shown by Dr. Gitis's test, is still further evidence that the silicone coating does permeate the braid, thereby facilitating movement between fibers within the braid. Ex. 11.

Further, Mr. Lyon testified that FiberWire is coated *twice* to make sure the coating is effective. As Mr. Lyon explained, the coating fills in the voids better when it is coated twice as compared to being coated once. Ex. 3 at 558:9-11.

The jury, of course, was free to accept this evidence, a sufficient basis to deny DePuy Mitek's motion. But the jury was also free to reject DePuy Mitek's testimony presented by Dr. Brookstein, who, the evidence showed, was unqualified to render *any* opinions on coating's impact on suture properties. As Dr. Brookstein admitted, he had no background in this area; his *only knowledge* regarding the impact of coatings on suture came *in conjunction with his work in this case.* Ex. 3 at 315:10-21. [Emphasis added].

Further, the testimony at trial showed that DePuy Mitek's "evidence" that FiberWire's coating does not permeate the braid, principally Dr. Brookstein's testimony about his SEMs, was completely unreliable. Dr. Mukherjee explained that SEMs are *not* generally used in the suture industry to look for coating on sutures; and especially not silicone coating as is used on FiberWire. As Dr. Mukherjee explained, silicone coating is transparent and colorless so it does not appear in SEMs. He also testified that a person with experience in reviewing suture micrographs who wanted to review them for the presence of a coating would have applied a pigment to make the coating visible in the micrographs. Ex. 3 at 740:24-741:3. Dr. Brookstein (who had never used an SEM on sutures before this case) did not do this. Ex. 3 at 346:9-18; 739:18-740:5; 742:3-8.

In addition, on cross-examination at trial, Dr. Brookstein admitted that during his deposition, he was *not* able to see coating anywhere on the surface of a commercial FiberWire suture *that had been coated twice*, *nor could he tell whether the coating partially impregnated the braid*. Ex. 3 at 352:7-353:15; 356:2-18. In other words, his trial testimony was *entirely inconsistent* with his prior deposition testimony. Moreover, Dr. Brookstein admitted that *he used different angles and magnifications* on the SEMs he showed to the jury purporting to compare a twice-coated FiberWire sample to an uncoated FiberWire sample and he used *different pictures* in his expert report from those he used at trial. Ex. 3 at 350:2-11. For all these reasons, the jury rightfully rejected Dr. Brookstein's SEM "evidence."

DePuy Mitek also asserts that Dr. Brookstein found FiberWire's coating did not permeate the braid because the suture contains less than 5% coating by weight. Mitek Mem. at 16. This evidence likewise proves nothing. Dr. Brookstein admitted at trial that he does not know how the 4.8% coating he purportedly measured on FiberWire compares with other sutures or even whether it is considered a "small amount" in the suture art. Ex. 3 at 360:14-17. For all these reasons, the jury was free to reject Dr. Brookstein's evidence.

VII. CONCLUSION

For all the foregoing reasons, DePuy Mitek's motions should be denied.

Dated: October 18, 2007

Respectfully submitted,

By: **/s/Charles W. Saber**

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing DEFENDANTS ARTHREX, INC.'S AND PEARSALLS LTD.'S OPPOSITION TO DEPUY MITEK'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50 AND MOTION FOR A NEW TRIAL was served, via the Court's email notification system on the following counsel for Plaintiff on the 18th day of October 2007:

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/s/Charles W. Saber

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff	)	
-VS-	)	CA No. 04-12457-PBS
	)	Pages 1 - 35
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ. and MICHAEL J. BONELLA, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
June 19, 2007, 2:50 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

asked him that.

THE COURT: What does your expert say?

MR. SABER: Well, our expert relies upon what everyone in the marketplace says, which is all the patents --

THE COURT: But did your expert do his own testing and say that it made a material difference?

MR. SABER: No, our expert didn't.

THE COURT: I disagree with either side's position that I can do it off of the specification because the specification says all things to all people. It can help; it can hurt. I mean, I think you have to look at the specific product to see whether it makes a material difference.

MR. SABER: Actually, I'd agree with that. I think that this notion of looking at the patents probably doesn't answer the question. It comes down to the question of the evidence.

THE COURT: So if you don't have a doctor or an expert who's tested it in a surgical setting and says it makes no difference --

MR. SABER: Well, we do. Of course, Dr. Burks did that, though we weren't the ones that offered that for purposes of summary judgment. The other side did. He got it right every time. But that's not the test. The test really is, this is what one of ordinary skill would mean. And that's where every teaching and everything that's known in

They're not significantly sacrificing the physical properties of the constituent elements of the suture.

And, if you remember, Arthrex's proposed construction used different language. They wanted you to rule that it would not significantly affect the physical properties of the suture. And your Honor's construction, which we contend is correct, is that whatever this additional element is, it cannot sacrifice the physical properties of the constituent elements of the suture, and that's what Dr. Brookstein says in his declaration.

THE COURT: I think Dr. Brookstein's declaration is certainly relevant. It's just not a bingo for you because he doesn't actually check to see whether it improves the pliability and handleability.

MS. ELDERKIN: With all due respect, your Honor, I don't know that that is really the issue under this construction of basic and novel characteristics.

THE COURT: It's both. It's got to improve the handleability and pliability without impeding or sacrificing the physical properties. So he tells you it isn't sacrificing anything, but if it also improved handleability, wouldn't that take you out of the infringement under a "consisting essentially of"?

MS. ELDERKIN: Under this construction of basic and novel characteristics, I would argue that it would not.

THE COURT: I'm not sure I agree, but, in any event, what other issues are left in this suit? Let's say I went to trial on infringement. Are there other defenses?

MR. SABER: Oh, yes, your Honor. I mean, if we go to trial, not only do we have the issues that we've been talking about today, but then there's the whole series of invalidity defenses and inequitable conduct defenses. As you may remember --

THE COURT: So is there obviousness and then possibly anticipation?

MR. SABER: That's correct, that's correct. Now, we moved on one anticipation grounds. There actually are several invalidity grounds that were put forward, but we didn't put them in a motion to your Honor. The one that we did put into a motion, your Honor, on anticipation on the Chesterfield patent, your Honor denied that motion. The other side had a motion on the inequitable conduct piece. Your Honor also denied that as well.

THE COURT: The inequitable conduct I'll put into the "manana" world.

MR. SABER: Well, at the end of the day, it's something for the Court to determine, correct.

THE COURT: Right. So if I were to do a trial just on infringement, would that make sense, or should I do it on everything, because it sounds like a little infringement

Exhibit 2

82 F.3d 434
82 F.3d 434, 1996 WL 128262 (C.A.Fed.), 39 U.S.P.Q.2d 1219
(Cite as: 82 F.3d 434, 82 F.3d 434 (Table))

H

Molnar v. IKG Industries
C.A.Fed.,1996.
NOTICE: THIS IS AN UNPUBLISHED OPINION.(The Court's decision is referenced in a "Table of Decisions Without Reported Opinions" appearing in the Federal Reporter. Use FI CTAF Rule 47.6 for rules regarding the citation of unpublished opinions.)
United States Court of Appeals, Federal Circuit.
W.S. MOLNAR COMPANY, Plaintiff/Cross-Appellant,
v.
IKG INDUSTRIES, a division of Harsco Corporation, Defendant-Appellant.
Nos. 95-1352, 95-1364.

March 21, 1996.
Rehearing Denied May 6, 1996.

E.D.Mich.

AFFIRMED.

Before LOURIE, CLEVENGER, and BRYSON, Circuit Judges.

DECISION

LOURIE, Circuit Judge.

***1** IKG Industries, a division of Harsco Corporation, appeals from the decision of the United States District Court for the Eastern District of Michigan denying its renewed motion for Judgment as a Matter of Law (JMOL) or, alternatively, a new trial. W.S. Molnar Company cross-appeals from the district court's denial of its motion for enhanced damages and attorney fees. *W.S. Molnar Co. v. IKG Indus.*, No. 93-CV-60028-AA (E.D.Mich. Mar. 31, 1995). Because the district court did not err in denying IKG's and Molnar's post-trial motions, we *affirm.*

DISCUSSION

Molnar owns U.S. Patents 4,961,973 and 5,077,137, which are directed to a grit-free slip resistant coating for a surface and a process for making the coating. Molnar sued IKG for infringement, and a jury found that the patents were not invalid and were willfully infringed. At the close of Molnar's case, IKG had moved for JMOL with respect to the patent count, providing no details. At the close of all the evidence, IKG moved for JMOL on infringement only, questioning whether it met the hardness limitation in the claims. After the jury returned its verdict, IKG renewed its motion for JMOL and alternatively moved for a new trial, and Molnar moved for enhanced damages. The district court denied IKG's motion, holding that IKG had not properly preserved its right to move for JMOL on the validity issues, the jury's infringement finding was supported by substantial evidence, and each party had received a fair trial. The court also denied Molnar's motion, holding that, although the jury found willful infringement, most of the evidence of copying involved pre-issuance activity; the other evidence did not justify enhanced damages.

On appeal, IKG argues that a new trial is required in view of our decision in *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 34 USPQ2d 1321 (Fed.Cir.) (*en banc*), *cert. granted*,116 S.Ct. 40 (1995), which issued after the trial. We do not agree. IKG agreed to a jury trial and did not object to the jury instruction regarding claim interpretation. IKG thus waived its right to have the claims construed by the district court judge.

IKG also argues that it preserved its right to move for JMOL on the validity issues and that the patents are invalid. We disagree. Rule 50 requires that a motion for JMOL "shall specify the judgment sought and the law and the facts on which the moving party is entitled to the judgment." Fed.R.Civ.P. 50(a)(2). IKG did not do this. A general reference to a count, which is the most that IKG can be said to have provided, is insufficient to meet the rule's requirements. *E.g.*, *Libbey-Owens-Ford Co. v. Insurance Co. of N. Am.*, 9 F.3d 422, 426 (6th Cir.1993). Rule 50 also requires that a motion for JMOL be made at the close of all the evidence in

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order for a party to renew that motion after entry of judgment. Fed.R.Civ.P. 50(b). Even if IKG were to be given the full benefit of its JMOL motion at the close of Molnar's case, it did not preserve its right to a post-trial renewal of a JMOL motion on validity. The rule required it to state its motion with specificity and it did not do so with respect to validity. Furthermore, contrary to IKG's assertion, the transcript of the court proceedings does not indicate that IKG was cut off by the district court. Even if it was apparent that the JMOL motion would be denied, it was incumbent upon IKG to clearly establish in the record the grounds for any later motion.

***2** IKG also argues that the district court erred in denying its motion for JMOL on infringement. According to IKG, the jury's finding of infringement is not supported by substantial evidence. The disputed claim limitation specifies a range of hardness (macrohardness) on the Rockwell C scale. Although the Rockwell C macrohardness of the accused product could not be directly measured, there was evidence that its microhardness could be measured and converted to macrohardness. According to expert testimony, conversion to obtain Rockwell C macrohardness is well known and used in the art, and the accused product had the hardness that met the claim limitation. Moreover, IKG's brochure describing the product specified an approximate Rockwell C macrohardness value for the product in the range specified by the claims. The jury's infringement finding is thus supported by substantial evidence. *See In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1532, 25 USPQ2d 1241, 1245 (Fed.Cir.1992) ("Fact findings reviewed under the substantial evidence standard require affirmance unless appellant shows that no reasonable juror could have reached such a result."). Accordingly, the district court did not err in denying IKG's motion.

IKG also argues that the district court erred in denying its motion for a new trial under Fed.R.Civ.P. 59. IKG argues that the jury's verdict was against the great weight of the evidence concerning its invalidity defenses, particularly its best mode defense. We do not agree. When a party has not properly preserved an issue in a motion for JMOL, we review the jury's verdict for plain error. *See Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 854, 20 USPQ2d 1252, 1255 (Fed.Cir.1991), *cert. denied*,504 U.S. 980 (1992). Although IKG submitted strong evidence of a best mode violation, we cannot conclude, considering our standard of review, that the jury's verdict constituted plain error. In addition, there is no indication that IKG did not receive a fair trial. Accordingly, the district court did not err in denying IKG's motion for a new trial.

On cross-appeal, Molnar argues that the district court abused its discretion in denying its motion for enhanced damages and attorney fees. According to Molnar, the court erred by substituting itself for the fact finder when it stated in its opinion that it would have found differently from the jury on willful infringement. Molnar also argues that IKG copied the invention and did not obtain an opinion of counsel. However, nearly all the activities supporting Molnar's assertion of copying occurred before the patents issued. Moreover, the evidence tends to show that IKG had a good faith belief that the patents were invalid in view of prior art, and an opinion of counsel is not an absolute prerequisite to avoiding willful infringement. Thus, the district court properly considered the various factors and did not abuse its discretion in denying Molnar's motion.

C.A.Fed.,1996.
W.S. Molnar Co. v. IKG Industries, a Div. of Harsco Corp.
82 F.3d 434, 1996 WL 128262 (C.A.Fed.), 39 U.S.P.Q.2d 1219

END OF DOCUMENT

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Exhibit 3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS Pages 143-290
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY TWO

BEFORE THE HONORABLE PATTI B. SARIS

UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 7, 2007 9:02 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

surgeons tie these knots over and over and very small vessels deep in the body, so if the suture is overly stringy or stiff or you can't tie a knot and it's not secure, those are issues that silk have some very nice properties.

Q. And what other kind of sutures were on the market other than silk?

A. So other products came along even though silk, it was still not very strong and some people were getting an inflammatory response when you put silk in, so the synthetic fibers like polyester and nylon came to market both in an uncoated form and coated form and those in addition to the dissolvable or the braided sutures, that dominated the market.

Q. Can you tell the jury what were the characteristics of the polyester sutures that were on the market?

A. The polyester sutures, the benefit of those, they were stronger so for some applications it was very important, and, again, they were maybe more bio-compatible. Again, some people react to silk in a negative way.

Q. How would you characterizes polyester sutures that were on the market in terms of their stiffness?

A. So they were clearly not as pliable or didn't have the handling properties that silk had, hence there was an opportunity if we could develop a new product that had both that handleability and the strength properties that we could

without melting or sticking the fibers together is what would give you the optimal properties.

Q. Thank you. If I could ask you to go to column 6, please, Dr. Steckel. I think you just read part of this. I just wanted to read it again. The sentence that begins at line I think it's 14 and goes to the end of that paragraph, "However, if the surface --" do you see that?

A. Yes.

Q. "However, if the surface of the heterogeneous braid is engineered to present a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving the expense as well as avoiding the associated braid stiffening." The conventional coating you're referring to here, is that the same conventional coating that plagues prior art?

A. That it is the same conventional standard coatings that everyone uses, the soaps, the silicones.

Q. I'm sorry.

A. Soap, silicone, what Arthrex, Johnson & Johnson, what everyone uses, yes.

Q. Okay. And it's best to eliminate those coatings, is that what your patent is teaching?

A. I'm saying there's a benefit of cost saving if you eliminate it, but it's not best. Really for sutures, it's the performance and for the patient account and the surgeon

more than the costs.
Q. And you're getting the benefits of the performance without the coating?
A. That particular property, knot tiedown you could get in this case with coating, but that's just one example.
Q. If I direct you to column 7 of your patent, Dr. Steckel, there are two examples listed there beginning on line 35 and going down to line roughly 64. Do you see that?
A. Yes, sir.
Q. Now, these braids, there are two different braids that were tested; is that correct?
A. Right. These would be examples of the invention.
Q. One of them was a braid made of PET and PTFE but a different braid of materials; is that correct?
A. That's correct.
Q. Another one is a braid of PTE and PTFE with a different percent of materials; is that correct?
A. One is 50-50, and the other is a 75-25 blend.
Q. And are these the configurations that you tested, Dr. Steckel?
A. These were examples of the braids, yes.
Q. And if you turn to column 8 beginning at line 36, there's a paragraph there that begins with, "Surprisingly"?
A. Right.

Q. Now, it says, "Surprisingly, the bending rigidity of the heterogeneous braids in Examples I and II do not follow the rule of mixtures." You're saying that you had superior results with these braids, correct?

A. Better than expected.

Q. Better than expected. Neither one of these braids was coated, correct, Dr. Steckel?

A. Correct.

Q. And if I turn you to the claims of your patent, beginning on the bottom of column 8 going to the end of column 10 the last two pages of your patent beginning at the bottom, do you see that?

A. Yes.

Q. Do you see the word "coating" anywhere in any of those 12 claims?

A. I would -- well, I would expect not.

Q. Thank you. Can I ask you to turn now, Dr. Steckel, to your exhibit, I'm sorry, there's a Plaintiff's Exhibit 520. That's your notebook.

A. 520?

Q. Yes, sir, that's your lab notebook. Can I ask you to turn to the page that's Bates stamped 2666. It's kind of near the end.

A. Yes.

Q. Now, you see it's actually on the screen, too. It might

be easier to read in front of you. You did read it earlier, I just want to go over it one more time and ask you a question. The composite, the last sentence of that paragraph says, "The composite also ranked better than the silk and Ethicon and knot tiedown even without a coating." Do you see that?

A. Yes, that was a surprise. We were going after pliability, but we ended up with this nice add-on.

Q. Doesn't this say that you don't need a coating on the suture you made?

A. On this one particular embodiment, you may not want to add a coating, but we talk about coatings through the patent.

Q. Now, Dr. Steckel, you said this particular embodiment, this particular embodiment was a combination of PTFE and PET or PT, and I know that's a lot of acronyms, ladies and gentlemen, but it was two different braids, isn't that right, of the PTFE and PET?

A. Yes.

Q. And the second combination was PP, polypropylene, and PET, correct?

A. Yes.

Q. Now, Dr. Steckel, you never tested a braid of the same materials as FiberWire; is that correct?

A. Polyester and polyethylene.

Q. Okay. Is this a demonstrative you use to teach with?
A. I have used not this particular one but the same one for almost thirty years that I've been teaching about yarn mechanics and bending and pliability of structures like these sutures. It's my touchstone.
Q. Can you explain with reference -- this is demonstrative Exhibit 613. Explain what you have in demonstrative Exhibit 613, and then we'll talk about the sutures, but let's just stick to the Exhibit 613. Explain the three sets of cards.
A. We have three sets of cards -- and I'm not going to do a card trick here -- we have three sets of cards and one set with 16 cards, and they're all individual, okay, 16 cards, and I punched a hole and secured them to this board, okay. Then I took over here the same 16 cards, and I glued each one together, so card 1 got glued to 2, 2 to 3, and so on. So these are all glued together. And then in the middle here I have a kind of an intermediate situation where I have 16 cards, but I've glued 1 and 2 together and 15 and 16 together.
Q. Okay. Now, with Plaintiff's Exhibit 613, can you explain the pliability concept to the jury.
A. Yes.
Q. And how it varies.
A. Remember earlier I talked about monofilament versus

multifilament. When they're all glued together, this would be an analog to a monofilament.

Q. You used the word "analog." What's that?

A. It would be a model. It would be similar to the -- it would be comparable to what you'd have if you had a monofilament where everything was all one structure, okay. So I did that.

This over here would be the example or similar to a multifilament where you had 16 individual materials, each one having its own set of properties, and you were going to see how that bent, okay. And then the middle one would be, all right, I'm going to have a little bit of coating, if you will, on the outside, so I'm going to glue 1 and 2 and 15 and 16.

Q. Now, how does the bending or pliability compare? Can you describe how that works?

A. Yes. Okay, and my hand is not calibrated, but, okay, that's -- they're free to slide by each other, okay? Here they're not free to slide by each other, okay? I can't bend that. This is very rigid. The same cards, but these are glued together. These are not glued together. And this one where it's just 1 and 2 are glued and 15 and 16, it's about the same as this.

Q. When you say about the same as this, you're referring to --

A. The one that 1 and 2 and 15 and 16 are glued together is about the same as they're not glued together. But you can see this, you can't --

(Witness indicating.)

Q. Now, how does that relate to the concept of bendability and pliability of FiberWire and what we've observed with respect to the FiberWire coating?

A. Well, we know FiberWire is made from multifilaments, and we can see from these pictures that the coating doesn't get into the structure. We can see that the coating doesn't bond the fibers together, okay? So these type of structures would be similar to these cards here that can bend. If the coating was into the structure, you'd have something like that.

(Witness indicating.)

Q. Okay. Now, in forming your opinion that FiberWire's coating does not have a material effect relative to the pliability in the novel and basic characteristics, does this relate to that?

A. Yes. Once I observed that the coating was not getting inside the structure and bonding these fibers together, then I knew that those fibers could act individually; and if they acted individually, it would be pliable.

Q. Now, does that go back to what we talked about before, the multifilament pliability and how that works?

A. Yes. These operate as multifilament structures where

there is lubricity and there's freedom of motion between the fibers.

Q. Now, when talking about freedom of motion, we had that demonstrative up there. We had the little circles, the little diameter of filaments. How does that relate to what we see in FiberWire?

A. That's what it is. That picture we saw is a schematic representation of what's actually the case of FiberWire.

Q. Now, can you give us an example of a FiberWire coating if it was on FiberWire, not FiberWire's coating but a hypothetical coating, that could have a material effect on the pliability of FiberWire.

A. Coating can have a material effect if it gets inside and bonds all these together, yes.

Q. But does FiberWire have that type of coating?

A. Not at all.

Q. Oh, one other question. With regard to the handleability and the smoothness of the structures, you were able to see the exterior, the peaks and valleys?

A. Yes.

Q. From your examination, did you conclude whether FiberWire's coating had a material effect on the smoothness and the bumpiness of the structure, the peaks and the valleys?

A. Yes. FiberWire's coating had no material effect on

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS Pages 381-429
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY THREE

BEFORE THE HONORABLE PATTI B. SARIS

UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 8, 2007 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

MR. SABER: It's just the yellow part. It goes over to the next page. Just the top part of that, the first two lines, the first three lines and the two lines from the page before.

Q. Did I ask you this question?

A. Excuse me, I don't know where.

Q. I'm sorry, page 165, line 24. It goes over to 166, line 3.

A. Okay.

Q. Now, did I ask you this question and did you give me this answer: "Would it be correct to say that what you've learned about coating and its impact on suture properties is in conjunction with your work on this case?" Answer: "That would be proper to say that, yes." Did I ask that question, and did you give that answer, sir?

A. At the time I told you I didn't remember if it was coated or not. I later found out it was coated.

Q. Sir, did I ask you that question, and did you give me that answer?

A. You did ask me that question, and I gave you that answer.

Q. Thank you. Now, you're, of course, being paid for your time that you put into this matter; is that correct?

A. That is correct.

Q. And you're being paid $300 an hour?

A. Show me where it says that.
Q. Okay. I apologize, I think I got the page wrong in my outline.
A. That's all right.
Q. Okay. Could you turn to page 223.
A. Yes, I can.
Q. Line 2.
A. Just give me a second please. Yes, sir.
Q. And I asked you, "Have you ever done it --" WE'RE talking about the scanning microscope, "-- on sutures before?" And you answered, "Not that I can recall;" is that correct?
A. Let me just look at the page before because I don't know what it is.
Q. Of course.
A. I said I couldn't recall at the time just like I couldn't recall what we did for U.S. Surgical, it was 20 years ago.
Q. Okay. Now, you told me where you hadn't used a scanning microscope before, correct?
A. Yes.
Q. You told me you used it on an air beam for the Army?
A. Yes, I used it on an air beam for the Army.
Q. And air beam replaces steel in a military structure; is that correct?

A. Yeah.
Q. And both of those are purporting to show -- 533 is purporting to show a cross-section?
A. That's what it shows, yes.
Q. Double coated?
A. Double coated, heated, stretched, yes.
Q. Now, you didn't show the same angle when you showed the uncoated one in 499; is that correct?
A. Not in those two pictures, that's correct.
Q. And they're not the same magnification, are they, sir?
A. They are not the same magnification, sir.
Q. Thank you. Now, at your deposition we discussed some of your pictures that you had done for the microscope. Do you remember that, sir?
A. I remember we discussed them.
Q. We discussed it, yeah. I'm just going to ask you a couple of questions about that, if you don't mind.
A. Sure.
Q. Right. Now, you had attached some pictures to an expert report that you had done in this case. Do you recall that, sir?
A. Yes, I did.
Q. Okay. And we talked about some of those pictures that were attached to your report. Do you recall that?
A. Yes, I do.

talk about your deposition.
A. I know to just see Exhibit G out there, I have to relate to it one of the pictures you gave me.
Q. I'm not sure if it is one of the pictures you gave. I think Exhibit G was something different you showed the jury.
A. I don't remember.
Q. I just want to ask you about what you told me at the deposition about the picture of the double coated FiberWire.
A. Okay.
Q. We've already established Exhibit G was a double coated FiberWire, right?
A. Yes.
Q. I said, "It's your opinion -- " excuse me, "Exhibit G, is it your opinion that there's coating on the surface?" Answer: "I can't -- the coating appears to be so small I can't even see it." Question: "You can't see it. So you don't have an opinion as to whether there's coating on the surface of G -- "
A. Correct.
Q. Answer: "I was presented --" Question: "From your observations?" Answer: "I was presented as a double coated specimen, and when I look for that, I look for coating, I don't see any, which later, when I measured and saw how much coating there was, it didn't surprise me that you didn't see it because it was so small." Question: "Okay. So is your

opinion is you can't see the coating on Exhibit G; is that your opinion?" Answer: My opinion is I haven't been able to see the coating, that's correct." Does that refresh your recollection that you told me that you couldn't see the coating on the sample that was double coated?

A. It refreshs my recollection, and I measured and I knew it was there but I couldn't see it.

Q. And then if you turn to line, page 252, line 13?

A. Yes.

Q. I asked you, "But it's your opinion the coating is on the surface even though you can't see it?" "No." "Is that your opinion?" "No. My opinion is I cannot see where the coating is on this at all."

A. Right.

Q. Is that what you said?

A. I could not see where it was on that.

Q. Right. Then you summarized line 19 on page 253. I said, "Right. But you can't testify here today where the coating is?" The answer is, is that correct?

A. You tailed off.

Q. I'm sorry, strike that. Could you go to 234.

A. Wait, you want me to go to page 234?

Q. 254, I apologize, sir, line 14.

A. Right.

Q. I asked you, "Can you tell me if it's not on the

and the lake.
Q. Sir, did I ask you these questions, and did you give me these answers? "Can you tell me whether it's partially impregnated, to use your term?" Answer: "No, I cannot." Question: "One way or the other?" Answer: "That's correct."
A. Excuse me, can you tell me where in the deposition?
Q. Page 256.
A. You didn't tell me that.
Q. I'm sorry, if I didn't tell you that, lines 15 to 19.
A. Okay.
Q. Did I ask you these questions, and did you give me these answers: "Sir, can you tell me whether it's partially impregnated, to use your term?" Answer: "No, I cannot tell." Question: "One way or the other?" Answer: "That's correct." Did I ask those questions, and did you give those answers, sir?
A. Yes, but you're taking it out of order.
MR. BONELLA: Can we have 254 4 through 7 with that?
MR. SABER: My question went to partially impregnation. This is something else.
THE COURT: Well, it's not even a full sentence.
MR. BONELLA: 4 through --
THE COURT: It's got to be 4 through something

Q. Now, you never did any study as to what percentage of weight is typical for coated sutures; isn't that correct?
A. There is no typical.
Q. Sir, did you do any study?
A. No, because there's no typical.
MR. SABER: Your Honor, could you please ask him to answer my questions.
THE COURT: The answer is no. What's the next question?
Q. Now, you have no knowledge of the percentage by weight of coating that is found on sutures other than FiberWire; is that correct?
A. I have no basis to know. I have no reason to know.
Q. Okay. You have no knowledge as to whether 4.8 percent is a small amount of coating compared to other sutures; is that correct?
A. Compared to other sutures, I would not know.
Q. Okay. Now, you would have had to do a test to know if surface coating of 4.8 percent can affect the knot tiedown characteristics of a multifilament braided suture; is that correct?
A. No, again we conclude heating and stretching, it's not just the coating.
Q. Sir, could you answer my question?
A. I'll try.

Q. Do you know of any uncoated sutures that are currently on the market?
A. I think there may be many sutures that don't have coating.
Q. Do you know of any uncoated sutures that are currently on the market?
A. I wouldn't be able to say I know this is an uncoated suture, no.
Q. Can you specifically name any uncoated suture that you've used in a surgical environment?
A. No.
Q. Okay, moving on to Paragraph 9 of Exhibit 232, you state: "In March, 2006, I received two samples of suture labeled Suture A and Suture B. Each sample was on a spool and it was approximately 3 meters in length." Do you see that?
A. I do.
Q. Who sent you the two samples you refer to in Paragraph 9 of Exhibit 232?
A. I believe I received them from a company in California.
Q. Do you know the name of that company?
A. I don't.
Q. Does the name CETR mean anything to you?
A. Only in that I think that Sal had mentioned that they had done tests or had been somewhat involved with the suture,

Q. And now can you explain what you're doing, Dr. Burks.
A. Same thing.
Q. With which exhibit?
A. 286.
Q. Are you doing the same thing you did with --
A. Yes.
Q. -- the previous one? The same knot configurations?
A. Uh-huh.
Q. Can you tell a difference between the first two sutures, Dr. Burks, Exhibit 285 and --
A. 286.
Q. -- and 286?
A. I'll let you know in a minute.
Q. And can you explain for the record, please, what you're doing now, Dr. Burks.
A. I'm tying 284
(Discussion off the record.)
A. Okay, so where's my little sheet here?
Q. Now, based on what you've done so far, Dr. Burks, can you tell any difference between the sutures?
A. I feel like I do feel a difference.
Q. Okay. How would you describe that difference?
A. Well, I would say at the moment 285 seems a little smoother to me than 284.
Q. Okay.

A. So I would say 285 is coated, and I would say 284 isn't coated.

Q. How sure are you of that?

A. I would not put my children's life on it, but given the subjective feel.

Q. Is it a subtle difference or is it --

A. It's a subtle difference.

Q. And can you explain, Dr. Burks, what you're doing now?

A. Just throwing knots. So I would say, for me, 286 seems coated as well.

Q. If you had gloves on right now, would that change the confidence level you have in determining whether those are coated or uncoated sutures?

A. I think gloves can make a difference, yeah.

Q. How do they make a difference? The difference between the sutures is more subtle, right, with gloves because you don't have the contact like you described earlier with the skin?

A. Yeah. Again, this is obviously a very subjective feel test. Some of that feel comes from how the suture feels, and some of it comes from how you feel when you slide a knot. And so we're not talking rocks and water as far as differences, and so. . .

Q. Well, how would you qualify the difference that you just observed based on your test?

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation, Plaintiff	)	
-VS-	)	CA No. 04-12457-PBS
	)	Pages 430 - 522
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY FOUR

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania, 19104-2891, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 10, 2007, 9:00 a.m.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
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(617)345-6787

and with gloves on. And my feeling was, it had too much friction, too much drag, and I was having a lot of trouble tying knots with it that were secure.

Q. Okay. Did you talk to Mr. Grafton about your observations on the handleability aspects?

A. Yes.

Q. And what did you tell him?

A. Well, I told him that, you know, I liked his idea of a high-strength suture, obviously, but he was going to have to basically get some better handling characteristics, have it so it had better run-down basically when you try to push the knot down, and that he was going to have to, as you would expect on any braided suture, have a coating to it.

Q. Did you have a discussion with Mr. Grafton about the need to have a coating on FiberWire?

A. Yes.

Q. Okay. Now, those discussions that you had with Mr. Grafton about the need for coating, was that for however FiberWire was going to end up?

A. Oh, absolutely. I mean, every braided suture worth its salt has a coating on it, so --

Q. And could you explain what you mean when you say that, that every braided suture worth its salt has to have a coating on it?

A. Well, the thing about braided suture is it's basically

bumpy, and it has a lot of friction. It has, you know, a high coefficient of friction relative to other types of suture; for example, the monofilament, which is just a single strand and doesn't have a lot of friction to it. So you have to have some way to smooth out the bumps, and a coating is a very tried and true tested type of way to do that.

Q. Now, I think you mentioned sliding through suture. Could you explain to the jury what that is? Sliding the suture and sliding through suture, you used a couple terms there.

MS. ELDERKIN: Objection. Expert.

THE COURT: Overruled.

Q. Go ahead, you can answer.

A. Well, the suture has to slide actually through a number of different interfaces. It has to slide against each other, so, you know, when you tie a knot, you have two suture strands. So if you have one braided suture strand against another suture strand, if they have a very high friction and a lot of bumps, you're not going to be able to slide them as well.

They also have to slide through soft tissue, so you're pulling your suture through, for example, tendon; and if it's too bumpy, it actually tends to cut the tendon. In fact, there are some mechanical saws that are based on that principle of having bumps on them. They actually can even

THE COURT: Can I see you at side bar.

SIDE-BAR CONFERENCE:

THE COURT: It may be I'm not understanding it, but he seems to have the expertise.

MS. ELDERKIN: He didn't put in an expert report.

THE COURT: It wasn't clear what the objection was. It sounded as if you're challenging qualifications.

MS. ELDERKIN: He has no expert report, and when we filed a motion to exclude him, Mr. Saber represented in the declaration he's not being brought to testify as an expert.

MR. SABER: When he had these conversations with Mr. Grafton, and we'll get into the killer idea in a moment, he has to explain what he meant by it and why he told Mr. Grafton what he told him.

MS. ELDERKIN: This is expert testimony.

THE COURT: I wish I had understood the basis for your objection better. I thought you meant he didn't have the expertise to say it. He certainly does have the expertise to say it.

MR. SABER: I'm almost done with it.

THE COURT: Now that I understand it, move on.

(End of side-bar conference.)

Q. Now, Dr. Burkhart, did there come a time when you had an E-mail exchange with Mr. Grafton about some of the ideas Mr. Grafton had for FiberWire?

A. Yes.
Q. And in that E-mail exchange, did you refer to some of his ideas as a "killer idea"?
A. Yes.
Q. And when you made those comments to Mr. Grafton, were you conveying that the suture did not have to be coated?
A. No.
Q. Okay, could you explain why you say that?
A. Well --
THE COURT: Say what, "killer idea"?
MR. SABER: No, why he wasn't saying that it didn't have to be coated.
A. Well, as we'd said from the very beginning --
MR. SABER: Say that it had to be coated. I'm sorry, your Honor.
A. Too many negatives in there.
Q. Sure.
A. From the very beginning when we tie tested that first uncoated product or uncoated prototype, I talked to Don and said, you know, "Do these have to be coated?" and he said, "Well, of course." I mean, that was understood from the beginning because you have to have something that has a low enough coefficient of friction that you can tie a knot that is secure and that isn't going to have that drag.
Q. And did that relate to what you explained about the need

to smooth out the bumps?

A. Exactly.

MR. SABER: I have no further questions, your Honor.

MS. ELDERKIN: Your Honor, if we could approach to put some exhibits on the bench for Dr. Burkhart?

THE COURT: Yes.

CROSS-EXAMINATION BY MS. ELDERKIN:

Q. Good morning, Dr. Burkhart. My name is Dianne Elderkin.

A. Good morning.

Q. Now, Dr. Burkhart, you weren't retained as an expert in this case by Arthrex, were you?

A. No.

Q. And you did not put in an expert report to advise the parties of your expert opinions before the litigation, did you?

A. No, I did not.

Q. Now, you testified that you tested an uncoated FiberWire prototype, but the prototype you tested was actually a prototype that was made of all PE, wasn't it?

A. My understanding, it was the ultrahigh molecular weight polyethylene.

Q. It had no PET in it, did it?

A. That's my understanding.

Q. And you found that that all PE suture did not have good

THE COURT: Sustained. Well, actually --

Q. Did you have an understanding as to why the testing was being done?

A. I had very limited understanding. I knew it was somehow related to patent infringement, but I didn't know a lot.

Q. What type of test did you decide to do?

A. We decided on a knot rundown test, and it's actually a test that's performed to determine the amount of force it would require to move a half hitch or start moving a half hitch down a line of suture.

Q. Can you explain what a half hitch is.

A. Yes. A half hitch is basically just the start of any type of knot. It's the first throw of any type of knot really.

Q. Why was a half hitch knot specifically chosen?

A. Because that's what surgeons use for all of their knots, all of their arthroscopic knot tyings that they do in the OR.

Q. Can you put up Exhibit 1357, please. Ms. Willobee, does this demonstrative accurately depict the test setup that you worked on?

A. Yes, it does.

Q. Can you describe the components of the test setup?

A. Yes, I can. I don't have a pointer, I think.

Q. I think you can touch the screen, Ms. Willobee.

A. Oh, okay. Let's start at the top. If you see where it

the chart, those two values are what you measured for the noncoated suture?

A. Yes.

Q. And what unit are these measured in?

A. This is measured in neutons. It's a measure of force.

Q. What do these other indications mean? "Mean, Std. Dev.," what do those mean?

A. Well, the mean is basically the average, so average meaning if you take the three samples and add them together and divide by three, you would have the mean or the average of 12.72 for the coated. And std. dev. is the standard deviation, and that just gives you an idea regarding the variance. If you have a large standard deviation, you have a large variance in your data. This is a small variance or a small standard deviation, so it means that the results themselves are pretty repeatable. And then minimum would be the minimum value out of that data set, and maximum would be the maximum value. Maximum value is 13.08.

Q. Thank you. Can you explain the difference that you recorded for the coated versus the noncoated?

A. Right. What we found is that there was basically two and a half times more force or load required to move the noncoated than the coated suture, and you can see that if you look at mean, 12.72 compared to 32.88.

Q. Thank you. If we could focus on the bottom graph,

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS Pages 523-682
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY FIVE

BEFORE THE HONORABLE PATTI B. SARIS

UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 13, 2007 9:04 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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A. Yes, it is.
Q. Could you explain how it was decided to coat FiberWire, your involvement in that, sir?
A. Well, pretty soon after we established that the mixture of the two materials would give us the knot security, then we said we'd go to various things we've got to do before this can be a suture, and one of them that it has to have a coating.
Q. Were you part of that decision on having to have a coating?
A. Oh, yes.
Q. Why did you believe it needed to have a coating?
A. Well, because a braid without a coating does not give you a good knot run-down and the surgeons would not be happy to have a suture like that.
Q. And so did you suggest a specific coating to use?
A. Yes, I did.
Q. And what coating did you suggest?
A. This was the Nusil 2174.
Q. And that suggestion came from you, sir?
A. Yes.
Q. And when you described why you suggested the coating, does FiberWire coating meet those goals?
A. Yes, it does.
Q. Okay. Now, you identified Nusil 2174. What kind of

and admitted into evidence as Defendant's Exhibit No. 1133.)

Q. In this patent that you're an inventor on, do you make any statements in this patent as to why coating is added to FiberWire?

MS. MALINOSKI: Objection, leading.

A. Yes, I do.

THE COURT: Overruled.

Q. Could you identify where in the patent that is?

A. It's in example 2.

Q. Okay. Is that the second column? It might be a little bit easier if you could identify the lines and the numbers so Derek can put it up on the board.

A. It's in column No. 2 in example 2, third paragraph which is line 48.

Q. Could you read to the jury what your patent says about why coating was added to FiberWire?

A. Yes, the suture is preferably coated with a silicone-based coating to fill in voids and provide optimum run-down.

Q. Thank you. Let me now turn to the process that Pearsalls uses to apply the coating to FiberWire. Were you involved in the development of that process?

A. Yes, I was.

Q. Could you -- we've developed, put an animation on this to perhaps help Mr. Lyon's testimony.

A. Yes, sir.
Q. Why do you go through the process the second time?
A. Well, when we were talking about it, we said that we could have one coating or two coatings. We've validated both. I remember discussing it with Mr. Grafton. He said well, which --

MS. MALINOSKI: Objection, your Honor.

THE COURT: Sustained.

Q. If you could just tell them why you do the two coatings.
A. Well, we felt it would fit in any voids in the braid better than if we did one.
Q. Now, when did Pearsalls start using silicone coating for its sutures?
A. 1986.
Q. Were you personally involved in that process?
A. Yes, I was.
Q. Could you explain what your involvement was in 1986?
A. The second biggest suture company in the world, Davis & Geck came to us and said --

MS. MALINOSKI: Objection, your Honor.

THE COURT: Sustained. You know, the basic concept is you can't tell us what somebody else said. That's hearsay.

THE WITNESS: All right. Even if he said it to me?

provided testing services and testing equipment to another huge manufacturer, United States Surgical, which is a division of Tyco Healthcare.

Q. Now, you talked about two different things, equipment and testing services?

A. Yes.

Q. Let me talk, and I want to concentrate specifically to suture manufacturers. What kind of equipment do you sell to suture manufacturers?

A. We sell our testing equipment called UMC2, universal market fibrometer, and we use it for both Ethicon and U.S. Surgical as well as for this case.

Q. Is the equipment that you sell to the suture manufacturers, is it all testing equipment?

A. Yes, it is.

Q. Do you develop any procedures that go along with the testing equipment?

A. We always do.

Q. Could you explain what that is, please?

A. You mean both our particular procedures?

Q. Yes, what kind of procedures, just generally?

A. Typically we develop procedures to test for such properties as friction, tissue drag test because we always test mechanical things like elastic modulars, tension, pliability and so on.

Q. Could you look at Exhibit 1252, please, kind of near the back of the book.
A. 1252?
Q. Yes. We'll skip over it.
THE COURT: All right.
Q. Dr. Gitis, have you ever seen your equipment on display at Ethicon, your testing equipment on display at Ethicon?
A. Yes, I have.
Q. Could you tell us about that, please?
MS. BONELLA: Objection, your Honor.
THE COURT: Sustained. Let's get to this case right now.
Q. You've also mentioned you've done some work on testing sutures before this case; is that correct?
A. Yes.
Q. Could you explain about that a bit? Who have you done those tests for?
A. Mostly for the same customers, Ethicon from Johnson & Johnson and U.S. Surgical from Tyco Healthcare.
Q. Could you explain generally?
THE COURT: No, we don't need that. Just jump into this case.
Q. Now, let's talk about were you hired to do some work in this case?
A. Yes.

A. Yes.

MR. SABER: Okay. Derek, could you put up the animation for the pliability. It's 1364.

Q. Dr. Gitis, could you explain what this exhibit is and how it relates to your pliability test?

A. This exhibit illustrates the setup and procedure we used to perform the liability test. The single suture was attached assembled vertically. The lower end was attached to the stationary clamp, and the upper end was attached to the for in some sense the moving up vertically, and by moving it up, the tension up, we continuously monitor more and more of the load and displacement which allowed us to calculate the stiffness of the suture.

THE COURT: What does pliability mean?

THE WITNESS: Pliability, it's opposite to stiffness, it's compliance of the suture.

THE COURT: So what's the difference between pliability and handleability?

THE WITNESS: I am not an expert in terms of this, but I can speak related to handleability.

THE COURT: Don't.

MR. SABER: I think, your Honor, you may want to save that for another witness.

THE COURT: I want to understand, the pliability test, what were you testing for?

THE WITNESS: Pliability, we test stiffness or compliance of the option, in this case, Fiberglas.

Q. Does this Exhibit 1364 accurately describe your test?

A. Yes, it does.

Q. I understand it's a demonstrative exhibit, but it does generally describe it?

A. It generally describes it, yeah.

Q. When you say on this exhibit, measurements used to calculate pliability, could you explain what you mean?

A. Yeah. As I said, the monitor force and vertical force and corresponding vertical displacement, and then we used common equations to calculate elastic and motion of inertia, which the product of each gives you the stiffness of the suture.

Q. Could you explain to the jury why you chose to use this pliability test?

A. We chose this test based on the literature, in particular, a well known paper by Professor George Rodeheauer from the Virginia University based on the publications by our customer, Ethicon, which is a division of Johnson & Johnson and based on our own experience testing sutures for Ethicon.

Q. Had you used this test previously for Ethicon?

A. Yes.

MR. SABER: Now, could you put up Exhibit 1371,

please.
Q. What is this exhibit, sir?
A. This exhibit on the left, it has the echograph, graph with the blue line is for the uncoated suture, the red line for the coated suture, and it just shows the force, displacement data of applied force on the corresponding elongation of the suture, and on the right, there is the summary data for this test. As I described, we conducted eight tests of the coated suture and eight tests of the uncoated suture.

There are results, stiffness results for each of them, and the last line of the table is average numbers, average for coated suture and average for uncoated suture. As you clearly see, there is more than 60 percent difference in stiffness or pliability or compliance between the coated and uncoated sutures.

MR. SABER: Derek, could you show the bottom line so the jury can see what Dr. Gitis is referring to.
A. Yes. So one of them has stiffness of 6 and the other has stiffness of 9, and as a statistical analysis confirmed, these are quite substantial differences.
Q. Now, in this test, this pliability test, any of the errors that you told the jury about, did they relate to this pliability test?
A. Yeah. I'm sorry, I didn't mention one more, I didn't

mention one error. In the regional report, we had a typo of describing the diameter of the suture. I wrote the diameter of 0.65, but in fact we measured it to be 0.56, so the diameter of the suture does not change the over 60 percent difference between coated and uncoated sutures, but it does change the ratio numbers.

Q. Okay. We'll get to that in just a second. Was there a second misreporting that related to the pliability test?

A. Yes. In my original report, I wrote that the test performed as a continually increasingly load but in fact looking at the test data, it's a test performed as continuously decreasing displacement.

Q. Did that reporting error, did that have any impact on either the numbers or the results?

A. No, it has no bearing whatsoever because the stiffness test, pliability test, tension test can be conducted easily with either increase in force measuring displacement or increase in displacement measuring force.

THE COURT: So we can't see the headings on these columns. So the coated is on the left and the uncoated on the right?

THE WITNESS: That's correct, ma'am, yeah. So coated suture has less stiffness which gives you more compliance and maybe one can speculate it's better for handling.

Q. Now, could you turn to Exhibit 1377, please, sir. It's going to come up on the screen. I think it's in third to last in the book.

A. Yes.

Q. Okay. What is 1377?

A. 1377, it's a Table 1-A which I presented in my supplemental report which re-calculates the same pliability that the individuals discussed, but it has the corrected diameter of the suture.

Q. So what is the comparison between the pliability numbers for the coated vs. the uncoated suture?

A. It makes no difference, it still stays the same. The coated suture was four and a half and for the uncoated suture the stiffness was 7.45, still over 60 percent of the suture pliability in the equation.

MR. SABER: Your Honor, I move to admit Exhibits 1377 and 1371.

MS. BONELLA: No objection, your Honor.

THE COURT: This is a good time for a break.

MR. SABER: It's a great time.

THE CLERK: All rise for the jury.

(THE FOLLOWING OCCURRED AT SIDEBAR:)

THE COURT: Just one housekeeping matter I wanted to mention, he's very difficult to understand with all the words that he uses so hopefully you're getting daily copy,

THE WITNESS: For some time, I understood it this way. It's not your American Indian tribes.

THE CLERK: All rise for the jury.

(Jury enters the courtroom.)

MR. SABER: May I proceed?

THE COURT: Yes.

BY MR. SABER:

Q. Welcome back, Dr. Gitis.

A. Thank you.

Q. Before the break we were talking about your tests, and I want to move to the next one, the knot slippage test. Now, I know you testified earlier that you were asked to look at knot security. Does knot slippage test relate to knot security?

MR. BONELLA: Objection.

THE COURT: Overruled.

A. To the best of my understanding, knot slippage test gives very good characteristic of knot security or knot strength, or whatever other terms are used.

Q. Okay. Could you turn to Exhibit 1365.

A. Yes.

Q. Could you explain what Exhibit 1365 is, this demonstrative exhibit?

A. It shows the -- it illustrates the schematics of our knot slippage test. It's different from the previously

described pliability test. In particular, now we have a knot on the suture, and also now we have a suture in form of a loop. If you remember in the tension pliability test, it was just a single suture. Now we've got a loop of the suture tied with a knot. And the lower end is wrapped around a stationary rod, and the upper end of the suture loop is wrapped around upper rod which is moving up vertically, exactly as it's shown here. And the sensor continuously monitors the vertical rod.

And to characterize knot slippage and knot security, we use two parameters; one parameter, the force at the very moment of the beginning onset of knot slippage; and the other parameter is the force at the knot failure. And typically in the literature, the knot failure is defined as either knot being untied or when slippage reaches and exceeds 3 millimeters.

Q. So do I understand you had to measure two different things; is that correct?

A. We monitored force, and we recorded two different values, two different levels of force, maximum force before slippage and then force at the moment of knot breaking.

Q. Now, what machine did you use to do this test?

A. We used the same UMT2 as we used for all other tests, and it's the same UMT2 which we sold to Ethicon, U.S. Surgical. We used our patented universal tester for all

suture tests.

Q. Okay. Now, let's move to Exhibit 1372.

A. Yes.

Q. What is this, Dr. Gitis?

A. This shows the results of our knot slippage test. On the left you will see is a graphical representation, and on the right you see the summary table. If you look at the plot, force versus time, you can clearly see that in the beginning, when you pull the suture loop up, force is increasing with time. Then at some moment of time, the knot begins to slip, and it creates force to the maximum force. So the moment of maximum force is detected as the characteristic of knot slippage.

And then we continue the test for at least three more millimeters, or until the knot is completely untied, and we record the other force value which corresponds to the complete knot failure.

Q. Okay. Could you explain how recording those forces relate to the chart that's on the right-hand side?

A. So those recorded forces are presented in the table. Again, as you remember, we tested eight samples of each, eight samples of the coated suture and eight samples of the uncoated suture. And for each, we recorded two values of force, at the onset of slippage and at the complete knot failure. And those values happen to be recorded in

kilograms. So the horizontal rows depict the corresponding values of the forces, and the very last row gives you the average values for the both eight forces.

As you can see, the coated and uncoated samples differed quite substantially, both at the onset of slippage and at the complete knot failure. At the onset of slippage, the coated samples showed knot strengths of about 3.3 kilo, and the uncoated samples showed over 5, 5.14 kilo. And at the same -- similar difference was observed at the knot failure, and the knot failure point, coated samples gave you an average strength of 2.5 kilo, and uncoated samples gave an average strength of 3.36 kilo. The differences are substantial, as later on confirmed by the statistical analysis.

Q. Now, just on this chart there's some plusses and minuses next to your averages. Do you see that in the bottom line?

A. Yes.

Q. Could you explain to the jury what that is.

A. In addition to showing the average values, this also shows the opposite of the variation, the fluctuations from sample to sample. So, as you can see, for example, from the first column, knot strength at slippage for coated samples, it was 3.3 plus/minus 0.95 kilogram, and for the second column, it was 5.14 plus/minus 0.67. This plus/minus gives you a good idea of the fluctuation of each and every number

around the average value for the eight-sample set.
Q. Okay. Now, I think you testified earlier that there would have been a reporting error on the speed that the test was conducted; is that correct?
A. Yes. In my report, I described the speed being one value, and after it was pointed out to me at the deposition, I looked more carefully and found the actual speed of the test had a different one.
Q. Okay. Now, the difference in the speed of the test, did that change your opinions or your results at all?
A. It changes neither results nor opinion, can change nothing but just minor description of the test procedure.
Q. Now, Dr. Gitis, let me turn to the next test that you did which was your knot run-down test. Derek, could you put up 1366, please. And could you describe this test for the jury, Dr. Gitis?
A. Yes. Knot run-down test, even though again we see a suture loop, we see vertical orientation of the suture, but it's quite different from the two previous tests. In the knot run-down test, we still have a knot, but the knot is somewhere in the middle of the suture. Above the knot there is just single suture, and below the knot there is a suture loop. And the idea, the goal of this test is to measure slippage of the knot, run-down of the half hitch knot when you tension the suture up. So the lower end of the suture

loop is wrapped around the stationary brass rod, and the upper end is clamped to the force sensor. Force sensor goes up vertically. And we measure knot run-down. We measure the force required to start knot going down on the suture.

Q. Okay, could you turn to Exhibit 1372. And could you, Dr. Gitis, could you explain what this is?

A. Yes. I'm sorry, we need knot run-down.

Q. Oh, I apologize, I apologize. It's my fault. 1369.

MR. SABER: Well, while we're on 1372, before you get it off, your Honor, I'd like to move to admit 1372.

MR. BONELLA: No objection.

(Defendant Exhibit 1372 received in evidence.)

Q. 1369.

A. Yes, 1369 describes the results of the test which we just saw the animation of. On the left we see is a plot of force versus time, and we see three examples for the uncoated suture and three examples of the coated suture. And you can clearly see that in the beginning when we were starting to going up and tensioning the suture, the knot was intact, and force was increasing. And then at some point the knot gave up and started going down, and force dropped. And while knot was sliding on the suture, we were measuring the -- we continued to monitor the force and measure knot sliding force.

Q. Okay, could you move to the chart, please.

A. And the summary of the results -- actually, all the results are presented in the table. And, again, we tested eight samples of the coated suture and eight samples of the uncoated suture. And the last row on the bottom shows average results and data fluctuation, and you can clearly see that coated sutures had the run-down force of about 0.22 kilogram, and uncoated sutures had the run-down force of about 0.40 kilogram, which is almost a two times difference. It obviously looks like coated suture has better slippage characteristics, and so it requires smaller force to start knot run-down.

MR. SABER: Your Honor, I move to admit Exhibit 1369.

MR. BONELLA: No objection, your Honor

(Defendant Exhibit 1369 received in evidence.)

Q. Could you turn now to your setup for your friction test, Exhibit 1367. Could you explain this, Dr. Gitis?

A. Yes. In the friction test, there are two suture samples. Both of them are assembled horizontally. The lower one is assembled around X axis, and the upper one is assembled around Y axis, so they are perpendicular to each other. One of them is moved back and forth over the other, and we continuously monitor the frictional force, force to resist the relative portion of one suture over the other suture.

Q. And what are you trying to measure in this test?
A. We are measuring the frictional characteristics, friction between friction of suture on suture.
Q. And could you turn to Defendant's Exhibit 1373. And what is this, sir?
A. These are the results of our friction test. As in previous slides, on the left there is a graphical representation, and on the right there is a table with the actual hard data. And if you look at the graph, first of all, you clearly see differences in levels of friction of uncoated, which depicts in black color, versus coated suture, which is depicted in red color.

Also, for the future, you can clearly see that uncoated sample has a larger magnitude of friction fluctuations than the coated sample, which was later used to characterize the chatter.

Q. Okay. Could you turn to the table, please. First, let me ask you, Dr. Gitis, there's this word of coefficient of friction at the top. Could you explain to the jury what that means?
A. Yes. The term "coefficient of friction" has been around for about five centuries. The coefficient of friction is a ratio of the friction force over the applied normal load.
Q. Okay, go ahead, explain the rest of the chart. Go ahead and explain the rest of the chart.

A. And if you see the data here, if you look at the eight rows, again, we tested eight coated samples, eight uncoated samples, coated over coated, uncoated over uncoated. And you can clearly see that the uncoated samples had very similar friction levels, with the average being 0.09 in friction coefficient; and all the uncoated samples had very close results, with an average of .16. So there's a really big difference in average friction between coated and uncoated sutures, which is later confirmed by the statistical analysis. And as you see, the deviations among all of the eight coated samples and the deviations among all of the eight uncoated samples are rather very small.

Q. Now, I think you told us before the break that you saw some inconsistency of the data, of the underlying data as it related to the friction test?

A. Yes. Unfortunately, the raw data file has some partial corruption into it.

Q. Does that issue with the underlying data affect your opinions about this friction test?

A. No, it doesn't. It cannot and doesn't affect my opinions because the results are very clear. The results look quite alike for coated and quite alike for uncoated. And I don't believe that any data corruption in the raw data file can shake my belief in these results.

Q. Now, what did you mean when you said that the coated

was -- the differences in the coated were very similar, very little, and the differences between the coated were very similar?

A. Well, because if you look again at the table on the right, you can see that the numbers don't really overlap. All coated samples produce friction coefficients between 0.08 and 0.10, which is quite remarkably consistent. And all uncoated samples produced friction coefficients from 0.15 to 0.17, which is also very consistent.

Also, the difference between friction of coated and friction of uncoated samples in this friction test corresponds very nicely to a difference in friction between coated and uncoated samples in the previously described --

MR. BONELLA: Objection, your Honor. Outside the scope of his expert report.

THE COURT: I didn't hear what you said.

MR. BONELLA: Outside the scope of his expert report. There's no comparison of other sutures in his expert report.

THE COURT: Yes, so ask another question.

MR. SABER: Okay. Well, Mr. Bonella's statement was just simply wrong. Okay, let's move on. I move to admit Exhibit 1373.

MR. BONELLA: No objection, your Honor.

(Defendant Exhibit 1373 received in evidence.)

Q. Okay, let me move to -- I think the next one you said was chatter. Could you show Defendant's Exhibit 1374.

Now, for the chatter, did you have to do a separate test, Dr. Gitis?

A. No. You don't have to reduce number of tests. We just, for chatter or amplitude of friction fluctuations, we just use the --

THE COURT: So what's chatter now?

THE WITNESS: Chatter is the amplitude of friction fluctuations. The term of "chatter" is very common not only for sutures but, for example, for your car brake. If your brake requires repair, you will hear chatter. Chatter means fluctuations in friction.

THE COURT: So what does it mean in the context of a suture, bumpiness of the braid?

THE WITNESS: Chatter means bumpiness of the suture.

THE COURT: I think we heard that five days ago, but I for one wasn't sure I remembered correctly. So when we're talking here chatter, it's bumpiness of the braid.

THE WITNESS: That's correct.

THE COURT: It's not very scientific, but at least I --

MR. SABER: It works for me.

THE COURT: All right.

Q. Okay, so what did you use to -- I know you didn't do a separate test -- what did you use to get the chatter results?
A. We just used results of the friction test and results of the tissue drag test. If we go back to the friction, to the friction -- blowups of the friction graph of the friction test results, you can clearly see that in addition to the average level of friction, from the same plot, you can get the amplitude of friction fluctuation. And the amplitude is the only and the direct characteristic of chatter.
Q. Could you go back to 1374, please. Okay, and could you explain the results here on this test?
A. Again, we compared eight samples of the coated suture, and we compared eight samples of the uncoated suture, and you can clearly see the difference in chatter. It's kind of well expected. If you have coating it, smoothens the bumpiness, as we just discussed. So coated suture exhibited chatter of just 0.009 in terms of friction coefficient, and uncoated suture exhibited chatter of 0.014, which is more than 50 percent higher. And the fluctuations from sample to sample are rather small. All eight coated sutures produced chatter from 0.008 to 0.012, and all the uncoated samples produced chatter from 0.011 to 0.019. So average one is differed substantially, which is later confirmed by statistical analysis.
Q. Let's turn to your last test, the tissue drag test on

1368.

A. Okay.

Q. And, again, Dr. Gitis, if you could just very briefly explain what is going on with this test.

A. The tissue drag test. So in the previous test we measured friction of suture on suture, but this test is measuring friction of suture against the tissue. And the tissue is simulated with the unfinished, unpolished piece of leather.

This slide just illustrates the test setup. The upper -- we use the single suture. The upper end was clamped to the force sensor, and the lower end was clamped between the two leather pads, tightly clamped together. And when we moved -- when we put the suture vertically up, the suture was rubbing against the leather, and thus we were able to measure the friction force and friction coefficient between the suture and leather, which simulates the actual body tissue.

Q. Okay, let's go to Exhibit 1370. And again if you could explain the results that you received on the tissue drag test.

A. Again, we can start from the plot on the left. The plot on the left shows force versus time dependencies for uncoated and coated samples. Uncoated samples are shown in black color, and the coated samples are shown in red, and you immediately see significant difference in the levels.

And in this test we measured two friction forces. We measured static friction force, and the definition of static friction force is the maximum force before the motion begins. And after motion started, after the initial start-up, we measured the average friction force during just slides in coated suture in the leather.

Q. Could you move to the chart, please, Derek. And if you could just get to the averages that are reported here. Could you explain what those are.

A. Yes. So, again, we report two forces, two friction forces or drag forces, static and dynamic. And static friction force for coated sutures was about .09, and static friction force for the uncoated sutures was about 1.18.

Q. And how about on the dynamic?

A. The same similar difference was observed with the dynamic values. The coated sutures exhibited lower drag force of about 0.5, and the uncoated samples exhibited a higher dragging force of about 0.78.

MR. SABER: Your Honor, I move to admit Exhibit 1370.

MR. BONELLA: No objection, your Honor.

MR. SABER: I believe I may have forgotten to introduce 1374, so I offer that as well.

MR. BONELLA: Which one is that?

MR. SABER: That's the chatter results.

MR. BONELLA: No objection, your Honor.

(Defendant Exhibits 1370 and 1374 received in evidence.)

Q. Could you turn to Exhibit 1378, please. Could you explain what this is, Dr. Gitis.

A. This is a summary of all the previous tables with test results. This shows only average values because only average values make sense in the statistical approach, and they show differences between average values for the coated and uncoated sutures. And you can clearly see that in the pliability data, there was over 60 percent difference between coated and uncoated.

Q. Before you move on, that over 60 percent difference, which one between the coated and uncoated had the better pliability?

A. The stiffness of the coated samples was over 60 percent lower than stiffness of the uncoated samples.

Q. For the jury, what does that mean on pliability?

A. Stiffness is reversed in proportion of the compliance and probably for the handling. So lower stiffness means better handling characteristics, better compliance of the suture in the hands of the surgeon.

Q. Okay, let's turn to the next one, knot run-down. Where it says 81 percent difference, what does that mean?

A. It means that the coated samples showed knot run-down,

showed knot run-down force almost -- over 80 percent lower than the uncoated samples, which is probably beneficial for the surgeon.

Q. Okay, which has the better knot run-down?

A. The coated samples have better knot run-down.

Q. Okay, the 77 on the friction, what does that mean?

A. It means that the coated samples had almost 80 percent lower friction than the uncoated samples, and the lower friction is probably beneficial. This is why they use coatings.

Q. Okay. Now, actually, Dr. Gitis, I'm really just asking you to show what the numbers show. We'll let another witness talk about the meaning of them. On the chatter, the 55 percent?

A. The 55 percent, we clearly see that the uncoated sutures had more fluctuations in friction force, more chatter, and the difference was 55 percent more chatter for the uncoated sutures as compared to the coated sutures.

Q. And how about the two numbers that were reported for tissue drag, static and dynamic?

A. Similar, similar situation. The coated samples had less both static and dynamic drag against tissue as compared to the uncoated samples.

Q. Okay. And the last two, the knot slippage, which I think you said related to knot security, those have a

negative number. What does that mean?
A. It means that for the coated samples, knot security turned out to be about 50 percent lower comparing to the uncoated samples.
Q. And just so the jury understands, which one did better, the coated or the uncoated?
A. On the knot slippage, uncoated did better, and the speculation is that because the coated samples had lower --
MR. BONELLA: Objection, your Honor.
Q. We can let another witness testify about that. I just wanted to know about the numbers that you did.
THE COURT: Are you almost done?
MR. SABER: Yes, about three minutes. I move to admit 1378.
THE COURT: All right.
MR. BONELLA: I have an objection, your Honor.
THE COURT: Can you say it here, or do you have to come up to side bar because we need to wrap up this witness?
MR. BONELLA: Well, how about side bar?
THE COURT: All right.
SIDE-BAR CONFERENCE:
THE COURT: What's the problem? It's just a summary like everything else was.
MR. BONELLA: We have an objection because we think he calculated his numbers wrong, which will come out on

cross.

THE COURT: Overruled.

(End of side-bar conference.)

MR. SABER: I move to admit 1378.

THE COURT: Yes.

(Defendant Exhibit 1378 received in evidence.)

Q. Could you turn to Exhibit 1379, please. Could you explain what 1379 is?

A. 1379 shows the results of the statistical analysis of all of the previous test data in terms of how statistically correct, how statistically significant are the differences between coated and uncoated samples in each of the performed tests.

Q. Now, the columns under coated and the columns under uncoated on chart, what are those?

A. The coated corresponds to the coated samples, and uncoated corresponds to the uncoated samples. And each column has two subcolumns. X stands for the average, Xc average for coated, Xu average for uncoated. And V stands for variance or fluctuation, Vc for the coated samples and Vu for the uncoated samples.

Q. And is that part of the data that you used to do your statistical analysis?

A. Yes.

Q. Okay, let me turn to the last two columns where it says

experimental "t" value and "T" threshold. What is being shown there?

A. Parameter T is calculated -- the "T" threshold is calculated based, typically practically taken from the handbook tables, based on how many samples you test. In this case, it was sixteen, eight coated and eight uncoated. And what degree of confidence, you choose. We chose 95 percent of confidence. For the confidence of 95 percent with the sixteen tests, the threshold value of "T" is 1.76.

Q. And could you explain the experimental "t" value quickly.

A. Experimental "t" value is calculated out of this -- can you please show the formula for experimental "t." The formula has on the two the difference between average values, and in the bottom it has total fluctuation, total fluctuation of coated and uncoated samples. So, roughly speaking, the experimental "t" shows how significant is the difference in mean average values versus total fluctuation of data.

Q. And going back to the chart on the experimental "t" values that you report, what is the significance of those numbers?

A. We can see that -- so in order to be statistically substantial, statistically correct, the experimental "t" has to be equal or greater to the threshold "T." And in all these tests, it was much greater than the threshold "T,"

which confirms the already-made observations that the differences between coated and uncoated samples for each of the tests were statistically meaningful and statistically substantial.

MR. SABER: Your Honor, I move to admit Exhibit 1375.

MR. BONELLA: No objection, your Honor

(Defendant Exhibit 1379 received in evidence.)

MR. SABER: And I have no further questions, your Honor.

THE COURT: Thank you.

CROSS-EXAMINATION BY MR. BONELLA:

Q. Dr. Gitis, I'd like to start with your pliability test.

A. Sure.

Q. In your pliability test, you first told us in your expert report that you performed that test at a 0.33 kilograms per second uniformly increasing load rate; isn't that correct?

A. Yes, sir.

Q. And that was incorrect?

A. Yes. It was the wrong time.

Q. And you learned that at your deposition when I deposed you, correct?

A. Yes. You were very careful.

Q. And when you signed your expert report, you thought it

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC. a Massachusetts Corporation, Plaintiff	)	
VS.	)	CA No. 04-12457-PBS Pages 683-904
ARTHREX, INC., a Delaware Corporation, and Pearsalls Ltd., a Private Limited Company of the United Kingdom, Defendants	)	

JURY TRIAL - DAY SIX

BEFORE THE HONORABLE PATTI B. SARIS

UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., MICHAEL J. BONELLA, ESQ., LYNN A. MALINOSKI, ESQ., and ANGELA VERRECCHIO, ESQ., Woodcock Washburn, LLP, Cira Centre, 12th Floor, 2929 Arch Street, Philadelphia, Pennsylvania 19104-2891, for the Plaintiff;

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 200006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
August 14, 2007 9:03 A.M.

LEE A. MARZILLI and VALERIE A. O'HARA
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205

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understand the needs of surgeons?
A. Absolutely. We always, even for the early part of the development phase, when we were making polymers, we always speak to surgeons.
Q. And why do you do that?
A. Because they're the customer. Like you develop something, whether it's a toy or a fabric or whatever, you look at who is using it and what the requirements are, and you try to satisfy those on met needs.
Q. Now, did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics of the '446 patent?
A. The coating -- what is your question again?
Q. Did you come to an opinion as to whether the coating on FiberWire affects the basic and novel characteristics that you see in the claim construction?
A. Yes, I did.
Q. What is your opinion?
A. That it does affect the basic and novel characteristics.
Q. Is that a material effect in your opinion?
A. It's a material effect.
Q. Now, when you rendered your opinions on this matter, did you render it from the position of one of ordinary skill in the art?

A. Absolutely.
Q. Could you explain what is the ordinary skill in the art here?
A. My experience, I hire a lot of people in the suture industry. They should have a science and engineering degree, about two to three years experience working in the suture company.
Q. Now, you see in the claim construction there's a term called "handleability" and term "pliability." Could you explain what that means?
A. Yes, sir.
Q. Sure.
A. Pliability is -- I'll give you a very simple example. If you take a small steel rod and you bend it, it's very stiff, but if you take a straw that you drink your soda, you bend it very easy, and that's pliability.
Q. How about handleability?
A. Handleability is a mixture of many things, but the first thing is the feel. And the suture, you give it to a surgeon's hands, how is the tactile feeling, then comes how does he tie the knot, what happens when the one strand goes with the other and then whether the knot is secure or not. All these things go in to handleability.
Q. Okay. How about as the suture is being used going through tissue, is that part of handleability?

A. Absolutely, absolutely.
Q. Okay. Now, I know we've had a lot of terms thrown around in this case, and I don't want to take long. I think the jury's start to get at, so perhaps if I could ask you a few of the terms you made, if you could just explain them to the jury. I think you talked about, just mentioned that a suture running down -- the knot running down the suture. What is that called, and can you explain that to the jury?
A. Knot run-down, this is one term used that when you -- especially when you do the arthroscopic knot, you tie the knot at the top, and the knot has to slide all the way down. That's the knot run-down.
Q. Okay. And how about the word, "chatter." You've heard that in this case. Could you explain what that is?
A. Yes. Chatter is whenever there is friction that it produces a lot of resistance, there's a measure of how rough the surface is.
Q. And I think suture slide, is that the same thing as the knot? What is suture slide?
A. Well, suture slide is a lot of different things because when you take one up strand and it goes with the other, it's a very important property. In fact, I learned, if I may say so, maybe I take a little bit of time, when I was developing polyethylene suture, the suture was breaking, and our straight pull and knot pull is much higher than our

competitor Ethicon, so I asked the product manager, show me how, why is the suture breaking because our measurements show that it's much stronger. Then he showed me what is going on. He take the one strand going with the other, when you tie the knot, and polypropylene is known for fibrillation, so it picks up the small fibers, and it breaks, so the surface, how the suture is stranded one over the other slide is very important property, by the way.

Q. Now, we've heard the term, "tissue drag." Could you just give a moment on tissue drag?

A. That is after let's say you succeed, suture is not rough, you can tie the knot, but, ultimately, proof of the pudding that it has to go through the tissue. Basically the function of the suture is to stick to the tissue, so if it is too stiff and too much resistance, the surgeons will not use it, so tissue drag resistance should be very low.

Q. Okay. Now, this case, of course, is about braided sutures, as I think we all know by now. Are there handleability problems that arise with braided sutures?

A. Absolutely.

Q. Could you explain what those are?

A. These are the like at first, give you an example of your uncoated, that when you tie the knot, it gets stuck and it does not slip all the way.

Q. Let me just ask you, is Dexon a braided suture?

A. Yes, I'm sorry, I should have said that. It's a braided suture, and the ease of tieing the knot is not there in an uncoated braided suture.

Q. And in your experience, how were these handleability -- are those handleability problems solved with braided sutures?

A. The only way that I know is put a coating on it. And most of the braided sutures, even today, they have coating if they are sold in the market. You can develop uncoated but don't do any good.

Q. Okay. I have a little animation here to talk about some of the things you've talked about knot run-down and the difference between coated and uncoated.

MR. SABER: Could you put up 1355, please.

Q. You may have a picture of it in your book.

A. Yes, I have it.

Q. Could you explain what this is, Dr. Mukherjee?

A. This is, you know, you are tieing the knot and you're pulling the two, what do you call it, eye of the sutures, two ends, and you pull it and you see how the knot travels all the way.

Q. Okay. We're going to show it kind of running here. Could you explain what the words that came up and what those, how that relates to an uncoated braided suture and with the knot run-down?

A. The uncoated, as I said, it will chatter. It goes and stops, goes and stops. That's the way you see the chatter. It's slower to use and a difficult knot to slide, and, moreover, the greater force to maintain, greater force to start. All the way it produces a lot of resistance for the surgeon.

Q. Now, I see the word, "slower to use." What is that referring to?

A. It's slower to get the knot where you want to put it in because, you know, the word we use, stick slip, it slips and sticks, that's the kind of thing that slows down the use of the suture.

Q. Could you turn to Exhibit 1356, which is the next animation.

MR. SABER; derek, why don't you run it first then we'll let Dr. Mukherjee explain. Could you do it again, please.

Q. Now, first let me ask you, we've shown you a couple animations. Are these exactly accurate?

A. Yes, close to, yes.

Q. This is just -- is this a depiction of what's going on, it's not the exact thing?

A. It's as close as you can get.

Q. Okay. Now, could you explain what's going on in this animation?

A. Okay. This is a coated braided suture. First of all, less chatter, not much of friction, and it's quicker to use because when you tie the knot, it goes, slides easily, doesn't feel that resistance and less force to maintain and less force to start. All of these are very important for a surgeon because he doesn't have time to fool around with the suture. His main mind is doing the surgery.

Q. Now, I want to talk a couple on the tissue drag and show a couple animations for you on that.

MR. SABER: Could you turn to animation 1362, please. I'm sorry, I might have given you the wrong. That one is 1363 on mine. I want the one for the uncoated one, Derek. The numbers got transposed, okay. Why don't you run it and we'll show what's going on here.

Q. Now, Dr. Mukherjee, could you explain what we saw on this tissue drag for uncoated braided suture?

A. This is another way of showing how difficult for the suture to go through the tissue even though the needle has made the hole, but because of these, this has been animated to show this like a saw that in order to produce through the tissue, you have to cut through the tissue, so it produces the damage plus, again, the surgeon really has to put effort to get the suture through the tissue. That's tissue drag.

Q. Now, you see the words, "sawing effect." Is that a term that's known in this art?

A. Yes.
Q. Could you explain what that is?
A. That's like, again, you know, again when you cut something, you feel, it goes and then stops, goes and then stops. That's the sawing effect. The surgeons always --
Q. Could you turn to I guess it would be 1362 in yours. Why don't we show this animation. Dr. Mukherjee, could you explain what this is?
This is a coated braided suture, and it requires less force because there's no roughness on the surface, and it allows a small incision. By the way, you have for different applications like if you do a plastic surgery or microvascular surgery, they're very, very small needles that are used, and this is a very important thing, small incision. There's less damage to the tissue and minimal injury to the tissue, and that's the whole thrust behind the suture, this whole arthroscopy is that that reduces the size of the incision. By the way, you may know this, arthroscopy was discovered here in Boston by our X, what do you call it, he was from India, Dr. Patel.
Q. Now, I think as you know we've had testimony in this case, the coating that's on FiberWire is silicone coating. Are you familiar with silicone coatings?
A. Absolutely.
Q. Could you explain how you've become familiar -- what is

Q. Now, was silicone used by Davis & Geck on braided sutures?
A. Yes, sir.
Q. Now, have you reviewed the patent literature as to how it relates to why coatings are on sutures?
A. Yes.
Q. Okay. And let me just go through a couple of those, if I may. We're not going to go through them all. Could you put up Exhibit 1100, please. Do you know what this is? Is this one of the patents that you reviewed?
A. Oh, yeah. He's a good friend of mine.
Q. Which one?
A. Bezwada.
Q. Let me ask you about the second guy, Alastair Hunter, do you know who he is?
A. I don't remember, but I used to know a lot of different people at that time.
Q. Do you know whether Mr. Hunter is the same inventor that's on the '446 patent?
A. Yes.
Q. Who's the assignee of this patent?
A. Assignee is Ethicon, Somerville, New Jersey.
Q. Let's turn to column 1. I want to draw your attention to the language. Could you read the highlighted portion?
A. "Surgery sutures often require a surface coating to

improve one or more of their performance properties. For example, multifilament suture typically requires a surface coating to improve the tactile smoothness, pliability and tiedown performance of the suture, so it passes easily and smoothly through tissue during operative procedures."

Q. Is this passage typical of the general understanding of what coatings do for sutures?

MS. ELDERKIN: Objection. Leading.

THE COURT: Overruled.

A. It does.

Q. Now, in your opinion is your opinion as you read this, is this passage talking about using coating on a specific suture, or is it a more generalized teaching of using coating on sutures?

A. No, sir. It's for general specific, it's not a specific one.

Q. Is it limited to any specific type of coatings, this teaching?

A. It does not.

Q. Let me move to the next one briefly. Could you move to 1101. Is this also one of the patents that you looked at?

A. Yes, sir.

Q. And is Ethicon also the assignee of this patent?

A. Yes.

Q. Okay. Could you turn to column 1. And is the

A. In fact, that's what it's used most, not absorbable sutures.
Q. It's usually used?
A. Yes, because silicone is nonabsorbable so they don't put absorbable sutures on a nonabsorbable coating.
Q. Okay, thank you. Now, did you review documents and testimony from Ethicon and Depuy Mitek in this case?
A. Yes, sir.
Q. Okay. I'm not going to take the time to put that stuff up now, but could you just generally tell the jury what you learned from your review of the Ethicon and Depuy Mitek documents and testimony.
A. If my memory serves right that the coating improves the performance of these braided sutures.
Q. Okay. In what kinds of performances?
A. Knot tiedown, tissue drag, all the properties, handleability, pliability that we talked about.
Q. Did it come as any surprise to you to see such statements made by the Ethicon Depuy Mitek witnesses and documents?
A. No, sir.
Q. And could you explain why?
A. Because that's generally accepted in the field.
Q. Okay. Now, let me turn to some discussion about FiberWire, in particular, if I could. As you know, I think

one thing that everybody agrees on that FiberWire has a silicone coating. Do you have any reason to believe that the coating on FiberWire, that its use is any different than what you just described to us as general teachings in the field?

A. No, sir.

Q. Okay. Could you tell, generally, the jury why you have that opinion?

A. Because my experience of more than 30 years, and I'm quite familiar with the suture performance properties, all those things plus the literature, that's what I based on my opinion.

Q. Now, have you seen any statements by Arthrex as to why or by Pearsalls as to why they use the coating?

A. Yes.

MR. SABER: Could you put 1106 up on the board, up on the screen, please.

Q. Is this one of the documents that you reviewed?

A. Absolutely.

Q. Okay. Could you identify what this is?

A. This is a product information FiberWire information from Arthrex.

Q. Could you read the highlighted portion, please.

A. "The suture is made of polyethylene fibers and polyester fibers braided, sterilized and coated for surgery use. The

coating acts as a lubricant for suture sliding, knot tieing, and ease of passing suture through tissue."

Q. Is this one of the documents that you used in forming your opinion about the material effect of FiberWire's coating?

A. Yes, sir.

Q. And could you tell the jury why, please?

A. Because this is exactly what I was talking about that the coating does improve, and silicone, there's a reason why silicone is used, and this word is "lubricant." You have a surface that is much lower than 30, in fact, '446 patent talks about that, so there's a specific property, lubricant.

Q. Now, have you seen any test results comparing coated and uncoated FiberWire -- let me ask you first whether you've seen any that Arthrex themselves performed?

A. Yes.

Q. And could you turn to Exhibit 1026, please. Do you have it there, Dr. Mukherjee?

A. Yes, I got it.

Q. Great. What is Exhibit 1026?

A. This is a test, I guess it's a report from Arthrex summary and signup sheet, and the testing was done by Ashley Holloway.

Q. Now, was Ms. Holloway in court and she testified last

A. That, again, the peak load with the resistance is about -- now again my math is not very good -- is about three times for the uncoated compared to coated.
Q. And what does that tell you as an expert in this field?
A. Uncoated is not a usable suture.
Q. The difference you described, is that an important difference?
A. Based on that data, yes.
Q. Is it -- okay. Is it a significant difference?
A. Well, that's why I was hesitating because I would not run only two samples in one, but the standard deviation is very low so that's the reason why I suggested to do the testing outside.
Q. Okay.
A. And Dr. Gitis did the testing.
Q. We'll get to that in just a moment. I just want to finish up with Ms. Willobee's test. Could you just explain why these, this kind of a test, how it relates to what actually goes on in surgery?
A. This is, again, I was trying to describe especially this product using arthroscopy surgery, and when the knot is tied at the top and you're sliding, if the load is too high, the doctor will feel a lot of resistance and he'll not use the suture so it's very important to have the big load lower,

Q. Okay. Let me turn to Exhibit 1379, if I could. 1379.
A. That's on the end.
Q. Yes, I think it's at the end. We'll make sure we get the right one up.
A. Yes.
Q. What is this?
A. This is a table, most meaningful table of the data. It gives all the property. Can you blow it up a little bit? No. Anyway the test on the left is stiffness, which is a pliability, slippage, strength, untie strength, run-down force, friction, chatter, static drag and dynamic drag.
Q. Now, the title of the table says, "Comparison of Values For Data Significance." What is the significance of this?
A. Yes. This is where we use the term, seems technical term, statistical significance, you know, if life would have been simple, every data would be the same, but it isn't, it will vary, so that's why you do statistical analysis, very important. You can't publish any information, any journal without this analysis.
Q. Okay. Now, is this what you -- is this -- strike that. Did you rely on this statistical analysis in forming your opinions?
A. Absolutely.
Q. And could you briefly explain from a statistical analysis point of view what is being shown in this chart?

Q. If you can, the last two columns, the T threshold and the experimental T value, I think that's what you're referring to?
A. Yeah.
Q. If you could try and make it so somebody like me can understand.
A. We do every day all the data, so I'm accustomed. What we're trying to do, the question is that is this average uncoated and the coated, are they significantly different, and this is a tool to determine that, and these values higher than the threshold value means significantly different. That's what in plain English that I can describe.
Q. Now, what is your opinion as to the statistical significance of what is reported in Dr. Gitis' tests?
A. That 95 percent confidence they're different.
Q. And is it a significant difference?
A. Yes.
Q. Okay. Now, could you turn to Exhibit 1378, please.
A. Yes.
Q. Now, did you hear Dr. Gitis talking about this chart yesterday?
A. Yes.
Q. Okay. Now, I don't want to go through it in great detail with you because he did, but what is this showing

Q. Now, does the heat stretching process help or hurt pliability?
A. The heat stretching hurts the pliability.
Q. Could you explain, give an example to explain why?
A. Best example I can give you, if I may, if you got a guitar string and you pull it all the way, it becomes very stiff, so that's what the stretching does to the stiffness.
Q. Does the heat stretching fill in those bumps on the braided suture, those rough surfaces?
A. There's no way.
Q. Now, in the report that you reviewed from Dr. Brookstein, did you make reference to his scanning electron microscope?
A. Yes.
Q. Did you review what he had to say about that?
A. Yes.
Q. Okay. Now, are you familiar with that equipment?
A. Very much so.
Q. And in your experience, is scanning electron microscopes used to look at sutures?
A. Yes.
Q. And have you -- is that something you've done?
A. We have done several of those.
Q. Okay. Could you explain why scanning electron

microscopes are used for sutures?
A. We -- as a lot of times the process of making suture used before that, we looked at the scanning electron microscopy and we see some damages. That kind of examination always goes on.
Q. And did you ever look with the use of a scanning electron microscope to look at the coating on sutures?
A. No.
Q. Could you explain why?
A. Coating, especially like a silicone coating is so transparent, it's colorless, so you cannot see anything.
Q. Now, did you ever have any discussions with your colleagues when you were at Davis & Geck as to what looking at a scanning microscope would show with respect to the coating?
A. Oh, yeah, because we were --
MS. ELDERKIN: Objection.
THE COURT: Overruled.
Q. Go ahead.
A. We were putting coating on Dexon sutures so we wanted to see at SEM nobody agreed, one person will say that there is, another person will say no, there isn't, so they were not really a very good test to find coating.
Q. If Dr. Brookstein had wanted to do a fair test with his microscope or something else, could he have done that?

A. The only way is to put pigment into a silicone, you may.
Q. And did he do that as far as you know?
A. No.
Q. Now, in your opinion, sir, would a person with experience using a scanning electron microscope for suture ever use such microscope for the purpose of seeing coating on a suture?
A. No.
Q. Now, there was also some, you know, in Dr. Brookstein's report that you reviewed for your report, did he opine that the coating did not permeate into the braid?
A. Yeah.
Q. Okay. Into the FiberWire braid?
A. Right.
Q. Okay. In your opinion, sir, does it matter to affecting the basic and novel characteristics of the '446 patent whether the coating permeates the braid?
A. It does not.
Q. And could you explain why?
A. Yeah. Silicone is a coating, and its properties are more or less, more than 100 times lower than the polyethylene, so the sum of the mixture is better in the direction making it more pliable so it does not matter where the coating is going to go.
Q. And how about for handleability, does it matter where

the coating goes?
A. No, it doesn't.
Q. Okay. Now, do you have an opinion as to whether in fact the coating on the FiberWire does get into the braid?
A. You know, it appears to me that it probably did.
Q. Okay. Why do you say that?
A. Again, this is I'm looking at the scanning microscope pictures. They appear to be there is something there. Now, I do not hang my hat on this observation. This is just kind of a, to some extent, stipulation.
Q. Now, are you familiar with I think you told me earlier that you're familiar with the coating process for braided sutures?
A. Absolutely.
Q. Is there anything in the braiding process that's used for braided sutures, coating process that's used in braided sutures that would allow you to come to the conclusion that the coating gets into the braid?
A. There is only thing because it's twice coated, there's a good chance it will get in and also the waking action, if you remember these little lamps that you put in the lamps and the oil goes up, that's the wicking effect so it may get in there from the operation itself.
Q. Could you explain a bit more about the wicking effect and what that has to do with coating processes for braided

sutures?
A. Like I gave you an example, you take the wick in the lamp, then there's oil in the globe, and the way the oil gets in through the scapular through what is called the wicking action, and the same thing will happen when designing solution is going into the braid.
Q. Okay. Now, in your experience with the coating process that you're familiar with, is the oven part of that coating process?
A. The oven is used only for curing because there is a cross-linking, now, again, confusing term probably.
Q. Could you take a moment and explain what cross-linking and curing is?
A. What it is, if I can show you is like a fisherman's net, no nets are made, they're not connected. When you put the connection between the two linear separate threads, that's cross-linking, and silicone, if you cross-link, silicone is going to wash away so there's a small amount of benzoyl peroxide. That's the chemical to produce that effect so that's why you need the oven to cure it, nothing else.
Q. Can you coat silicone coating without putting it through the oven?
A. No.
Q. Okay. The -- I want to ask you some about what Dr. Brookstein said about Mr. Grafton's testimony to support

A. Based on a lot of experience and testing of existing products.

MR. SABER: We have no further ones to read to the jury, your Honor. There are a couple which we will just be submitting for the record.

THE COURT: All right. And so?

MR. SABER: If I can just have a moment.

(Discussion off the record between defense counsel.)

MR. SABER: And subject to just submitting these additional deposition designations that I just mentioned, the defense rests.

MS. ELDERKIN: Can we see you at side bar?

THE COURT: Yes.

SIDE-BAR CONFERENCE:

MR. SABER: Excuse me. And may I add, your Honor, of course we have to respond to whatever is necessary to respond to.

THE COURT: Say it again?

MR. SABER: Also, you know, we'd like the opportunity to respond to anything further on the ownership issue, if it becomes appropriate.

THE COURT: Yes, I understand.

MR. BONELLA: Your Honor, they have a declaratory

judgment counterclaim for noninfringement, and we're moving as a matter of law on that counterclaim.

THE COURT: Denied. Okay, thank you. And so how long do you have?

MR. BONELLA: I think Dr. Brookstein, no more than ten minutes.

THE COURT: Ooh.

MR. SABER: I'm going to hold you to it, Mike.

(End of side-bar conference.)

THE COURT: The defense has rested, and now there will be a brief rebuttal testimony by Dr. Brookstein. Is that correct?

MS. ELDERKIN: Yes, your Honor.

MS. MALINOSKI: Yes.

THE COURT: Come on up, sir. You're still under oath. Thank you.

DAVID BROOKSTEIN

having been previously duly sworn, was examined and testified further as follows:

THE COURT: Oh, my gosh, look at these binders. I thought you wanted the jury to read those during deliberations.

MR. SABER: I want to see Dr. Brookstein read them in the amount of time Mr. Bonella said.

DIRECT EXAMINATION BY MR. BONELLA:

two-step process. The first step is to decide the meaning of the patent claim. I've already made this determination and will instruct you as to the meaning of the claim at issue here, and I showed you what that was on the patent. The second step is to decide whether defendants have made, used, sold, offered for sale, or imported within the United States a product covered by Claim 1 of the Hunter '446 patent. You, the jury, must make the determination about whether there's been an infringement, and that's what you're asked on the verdict form.

Now, the following claim terms -- and I'm once again referring back to Claim 1 in the patent that I handed out to all of you -- the following claim terms have the following meanings. You'll see in Claim 1 that there is the abbreviation PE. PE includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. You've sometimes seen that shortened as UHMWPE.

So let me say that again: PE as it is in Claim 1 includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene.

What do we mean by the "basic and novel properties" of the suture described in the Hunter '446 patent? You remember I handed that out to you on the very first day, and I hope you still have a copy of what I said it was so you

don't have to write it down, but I'm going to read it to you right now. The "basic and novel properties" of the suture described in the Hunter '446 patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim 1, (3) where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. You have that already in writing.

So to prevail on its claim, what does the plaintiff have to prove? To prevail on its claim, DePuy Mitek must prove by a preponderance of the evidence that defendants have made, used, offered for sale, sold, or imported into the United States the invention defined in Claim 1 of the Hunter patent.

A person can directly infringe a patent without knowing that what he is doing is an infringement of the patent. He may also infringe even though in good faith he believes that what he is doing is not an infringement of any patent.

Also, an accused product may infringe an asserted patent regardless of whether the accused infringer has its own later-issued patent on the accused product. In other words, the fact that Arthrex has a patent covering FiberWire

does not constitute a defense to infringement of plaintiff's Hunter '446 patent.

So now I want to discuss a very unique patent term, which is the term "consisting essentially of." You've seen that a lot and heard a lot about it, "consisting essentially of."

I call your attention to a phrase used in the Hunter '446 patent, "consisting essentially of," which has a very special meaning in patent law. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I've just defined them.

I'll repeat that again. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire's sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I have just defined them to you.

An effect on the basic and novel characteristics of an invention is material -- that's a legal term, "material." You've heard that term too. An effect on the basic and novel characteristics of an invention is material

if the effect is of importance or of consequence to those of ordinary skill in the art.

Let me state it again: An effect on the basic and novel characteristics of an invention is material if the effect is of importance or of consequence to those of ordinary skill in the art.

The only question here before you is the effect of the silicone coating. The only question here is the effect of the silicone coating. You will need to consider the evidence and decide whether the silicone coating on FiberWire has a material effect on the basic and novel properties of the suture.

Again, you will need to consider the evidence and decide whether the silicone coating on the FiberWire suture has a material effect on the basic and novel properties of the suture.

Mitek claims it does not have a material or important effect, and Arthrex contends that it does have a material or important effect.

To say it another way, the FiberWire sutures do not infringe the claims of the Hunter '446 patent if the coating on the FiberWire sutures materially affects the basic and novel properties of the invention, as I have defined it. Ultimately, you will have to decide based upon the evidence whether plaintiff has proven that the coating included in the

Exhibit 4

Hinz v. Neuroscience, Inc.
D.Minn.,2007.
Only the Westlaw citation is currently available.Dr. Martin HINZ and Neuroresearch Clinics, Inc.,
Plaintiffs,
v.
NEUROSCIENCE, INC. and Gottfried Kellermann,
Defendants.
No. 04-CV-0142(PJS/RLE).

May 31, 2007.

Aaron W. Davis and Brian L. Stender, Patterson Thuente Skaar & Christensen, PA, for plaintiffs.
Henry M. Helgen, III, Amanda R. Cefalu, and Carl S. Wosmek, McGrann Shea Anderson Carnival Straughn & Lamb, CHTD, for defendants.

ORDER

PATRICK J. SCHILTZ, United States District Judge.

***1** On October 10, 2006, a jury found defendants Neuroscience, Inc. and Gottfried Kellermann (collectively "Kellermann") liable to plaintiffs Dr. Martin Hinz and Neuroresearch Clinics, Inc. (collectively "Hinz") on Hinz's claim for breach of contract. The jury awarded Hinz $1,989,373.00 in damages, and the Court entered judgment on the jury's verdict.

This matter is before the Court on six post-trial motions: (1) Kellermann's motion for judgment as a matter of law or, in the alternative, a new trial; (2) Kellermann's motion for a stay of judgment; (3) Kellermann's motion for an extension of time to file a notice of appeal; (4) Hinz's motion for a permanent injunction, and for pre- and post-judgment interest; (5) Kellermann's motion for a stay of any permanent injunction granted pursuant to Hinz's motion; and (6) Hinz's motion for attorney's fees and costs.[FN1] For the reasons set forth below, the Court grants Kellermann's motion for judgment as a matter of law with respect to damages and denies it in every other respect. The Court also denies Hinz's motions for a permanent injunction and for attorney's fees and costs. The remaining motions are denied as moot.

FN1. The Court also previously granted Kellermann's motion for an order requiring Hinz to show cause why he should not be held in contempt for violating the Court's October 2, 2006 injunction. For the reasons stated at the February 20, 2007 hearing, the Court declines to impose any sanctions on Hinz for his one-time violation of the injunction.

A. Kellermann's Motion for Judgment as a Matter of Law or a New Trial

1. Sufficiency under Fed.R.Civ.P. 7(b)

Both Rule 50(b) (governing post-trial motions for judgment as a matter of law) and Rule 59(a) (governing motions for a new trial) require that these motions be filed no later than ten days after the entry of judgment. Kellermann filed Rule 50(b) and Rule 59(a) motions on the tenth day after judgment, but those motions did not describe the grounds on which they were based. The basis of the motions was described in a supporting memorandum, but that supporting memorandum was not filed until the next day-after the ten-day deadline had passed. *See*Docket No. 411 (motion filed Oct. 25, 2006); Docket No. 425 (noting that Kellermann's conventionally filed memorandum was received in the clerk's office on Oct. 26, 2006). Hinz argues that Kellermann's motions therefore failed to "state with particularity the grounds therefor" as required by Rule 7(b), and that this failing was not "cured" by the memorandum because the memorandum was filed after the ten-day deadline-a deadline that this Court has no power to extend. See Fed.R.Civ.P. 6(b)(2). Therefore, Hinz contends, Kellermann's motions must be dismissed under Rule 7(b).

Rule 7(b)'s particularity requirement does not apply to oral motions made during a hearing or trial, however. *See*5 Charles Alan Wright & Arthur R.

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Miller, *Federal Practice and Procedure* § 1193 (3d ed. 2004) ("Rule 7(b)(1) specifically exempts oral motions made during a hearing or trial from the requirements of particularity[.]"). At the close of Hinz's case, Kellermann properly made an oral Rule 50(a) motion and specified the grounds for the motion in court as well as in a written submission. Trial Tr. vol. III, 478-490, Oct. 6, 2006; Docket No. 382.After the jury returned its verdict, Kellermann orally renewed his motion under Rule 50(b). Trial Tr. vol. V, 577, Oct. 10, 2006. The Court immediately informed Kellermann that it would "take [the motion] under advisement and expect you to brief it ... as part of your post-trial motions."Thus, the motion now pending before the Court is the oral Rule 50(b) motion that Kellermann made immediately after the jury returned its verdict. As noted, the particularity requirement of Rule 7(b) did not apply to that oral motion.[FN2] *Cf. Meriwether v. Coughlin*, 879 F.2d 1037, 1041-42 (2d Cir.1989) (holding that the following statement, made after the jury returned its verdict, was sufficient to comply with Rule 50(b): "I would, your Honor, like to at this time note that defendants wish to move for a judgment notwithstanding the verdict").

> FN2. The fact that Kellermann later-and unnecessarily-reduced his Rule 50(b) motion to writing does not change this analysis. Obviously, by reducing his oral Rule 50(b) motion to writing, Kellermann did not *withdraw* the oral Rule 50(b) motion-a motion that the Court had under advisement.

***2** One might argue that exempting oral motions from Rule 7(b)'s particularity requirement would lead to the absurd result that a party could move for judgment as a matter of law without ever having to specify the grounds for its motion. But Rule 50(a)(2) requires that a 50(a) motion "specify the judgment sought and the law and facts that entitle the movant to the judgment," without regard to whether the motion is oral or written. The reason for this particularity requirement is to give the nonmovant the opportunity to introduce evidence sufficient to cure the claimed defect before the case is submitted to the jury. *See Canny v. Dr. Pepper/Seven-Up Bottling Group, Inc.*, 439 F.3d 894, 901 (8th Cir.2006). A Rule 50(b) motion is, by definition, a renewal of a Rule 50(a) motion. Thus, Rule 50(a)(2) has the practical effect of ensuring that the opposing party and the court will be apprised of the basis for any kind of Rule 50 motion.

Even if this analysis is incorrect-that is, even if Rule 7(b)'s particularity requirement *did* apply to Kellermann's Rule 50(b) motion-it is clear under *Andreas v. Volkswagen of America, Inc.*, 336 F.3d 789, 794 (8th Cir.2003), that the Court may look to Kellermann's *previous* filings to satisfy that requirement. Hinz argues that the written Rule 50(b) motion in *Andreas* was held to be sufficient only because the motion specifically alluded to one of the grounds raised in the Rule 50(a) motion. But the salient point of *Andreas* was the following holding: In the present case, the district court rightly looked to the Rule 50(a) pleadings. By definition, a Rule 50(b) motion is a renewal of a prior Rule 50(a) motion made at the close of the evidence and as such is limited to those issues raised in the previous motion.

Id. While *Andreas* pointed out that the written Rule 50(b) motion referred specifically to one of the four issues raised in the Rule 50(a) motion, it is not clear that *Andreas's* holding *depended* on that fact. Indeed, the Eighth Circuit has previously held:Once a sufficient motion for judgment as a matter of law has been made, nothing in the law requires the movant continually to make arguments or to file written motions repeating the details of the original over and over again. We believe that it is sufficient for the movant ... simply to renew the motion generically.

Kline v. City of Kansas City, Fire Dep't, 175 F.3d 660, 670 (8th Cir.1999).

Hinz contends that *Kline* is distinguishable because it concerned the sufficiency of the moving party's Rule 50(a) motion made at the close of all the evidence, rather than the sufficiency of a renewed motion under Rule 50(b).[FN3] But, as *Andreas* ex-

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plains, a Rule 50(b) motion is simply a renewal of a Rule 50(a) motion. If a Rule 50(a) motion can be "generically renewed" at the close of the evidence (as *Kline* held), then surely it can be "generically renewed" after the jury has returned its verdict.

> FN3. Although *Kline* cites Rule 50(b), it appears that the court was discussing only whether the moving party had properly made a Rule 50(a) motion at the close of the evidence. *See* *Kline*, 175 F.3d at 670 (discussing the motions made at the close of the plaintiffs' evidence, at the close of the defendant's evidence, and at the close of all the evidence).

***3** The Eighth Circuit has emphasized that technical precision is not necessary under Rule 50 or Rule 7, so long as the court and the opposing party are aware of the grounds for the motion. *Andreas*, 336 F.3d at 793;*Jarvis v. Sauer Sundstrand Co.*, 116 F.3d 321, 323 n. 4 (8th Cir.1997); *Cortez v. Life Ins. Co. of N. Am.*, 408 F.2d 500, 502-04 (8th Cir.1969). Here, the issue of damages raised in Kellermann's late-filed memorandum was also raised in his Rule 50(a) motion and was extensively argued throughout trial. When Kellermann orally renewed his motion after the verdict-and when Kellermann later (and unnecessarily) reduced that pending motion to writing-neither the Court nor the parties could have had any doubt regarding the basis for the motion. The Court therefore finds that Kellermann's Rule 50(b) motion is properly before the Court.[FN4]

> FN4. Because the Court has found that Kellermann's Rule 50(b) motion is sufficient, Kellermann's motion for an extension of time to file a notice of appeal is moot. *See*Fed. R.App. P. 4(a)(4)(A)(i) (a timely-filed Rule 50(b) motion tolls the deadline to file a notice of appeal).

The same is not true, however, for Kellermann's Rule 59(a) motion for a new trial. Kellermann did not move for a new trial under Rule 59(a) until ten days after the judgment, the final day for filing such a motion. *See*Docket No. 411.As noted, that motion did not describe the grounds on which it was based, and Kellermann did not file a supporting memorandum identifying those grounds until the next day-one day after the ten-day deadline. *See*Docket No. 425.The Rule 59 motion is therefore insufficient under Rule 7(b), and the Court is without power to consider Kellermann's request for a new trial.[FN5] *See*Fed.R.Civ.P. 6(b)(2); *Riley v. Nw. Bell Tel. Co.*, 1 F.3d 725, 727 (8th Cir.1993).

> FN5. Although Rule 50(b)(1)(B) grants the Court the discretion to order a new trial, that discretion exists for the benefit of the *nonmoving* party, so that it may remedy the lack of evidence that would otherwise require entry of judgment against it. *See* *Goldsmith v. Diamond Shamrock Corp.*, 767 F.2d 411, 414 (8th Cir.1985). In contrast, an alternative motion for a new trial under Rule 59(a) is for the benefit of the party moving for judgment under Rule 50(b). In the event that the party is not entitled to judgment under Rule 50(b), it can ask, in the alternative, for a new trial under Rule 59(a).*See*9A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* §§ 2538, 2539 (3d ed.2004).

Because Rule 50(b) expressly permits a party to jointly move under Rule 50(b) and Rule 59(a), Kellermann could argue that, to the extent that his Rule 59(a) motion presents the same issues as his Rule 50(b) motion, it is properly before the Court. But a Rule 59(a) motion can be based on any number of grounds, many of which would not be evident in the record of the trial. Simply invoking Rule 59 provides the Court with no basis on which to grant a new trial. The fact that Kellermann simultaneously moved for judgment as a matter of law under Rule 50(b) does not help him, because a Rule 59(a) motion is not equivalent to a Rule 50(b) motion. The standards applicable to the two motions are quite different. *See* *White v. Pence*, 961 F.2d 776, 779-80 (8th Cir.1992); 9A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 2531 (3d ed.2004). Indeed, courts

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carefully distinguish between the two motions: A party who moves only for judgment as a matter of law under Rule 50(b)-and whose motion is denied-cannot be granted a new trial on the basis that the verdict is against the weight of the evidence. *See Goldsmith v. Diamond Shamrock Corp.*, 767 F.2d 411, 414-15 (8th Cir.1985). The Court therefore concludes that the reference to Rule 59 in Kellermann's only timely filing is not sufficient to bring his Rule 59 motion properly before the Court. *See Riley*, 1 F.3d at 726-27.

2. Standard of Review

***4** Judgment as a matter of law is appropriate when a party has been fully heard on an issue and "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue [.]"Fed.R.Civ.P. 50(a)(1). In considering a motion for judgment as a matter of law, the Court must view the facts in a light most favorable to the nonmoving party and grant the nonmoving party the benefit of all reasonable inferences. *See Canny v. Dr. Pepper/Seven-Up Bottling Group, Inc.*, 439 F.3d 894, 899-900 (8th Cir.2006). The Court should not grant the motion unless the evidence is susceptible of no reasonable inference sustaining the position of the nonmoving party. *Children's Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 863 (8th Cir.2004).

3. Damages

This case arose out of a previous lawsuit between the parties that ended in settlement. The jury in this case found that the parties' settlement agreement, which they signed in September 2003, prohibited Kellermann from promoting, marketing, using, or selling any product that contains the ingredient mucuna pruriens. *See*Docket No. 392.During the trial, Hinz argued that he was entitled to lost profits in the amount of $5.5 million, Cefalu Aff. Ex. L, Oct. 25, 2006, but the jury awarded him $1,989,373.00. Kellermann argues that the evidence was insufficient, as a matter of law, to support any award of damages.

Under Minnesota law, a plaintiff may recover damages for lost profits if the claimed damages are not remote, speculative, or conjectural. *See Cashman v. Allied Prods. Corp.*, 761 F.2d 1250, 1252 (8th Cir.1985) (applying Minnesota law).FN6 A plaintiff need not establish the amount of damages with absolute certainty. As long as the *fact* of damage is proven by a preponderance of the evidence, the difficulty of calculating the precise *amount* of damage will not preclude recovery if there is a reasonable basis on which to approximate that amount. *See Polaris Indus. v. Plastics, Inc.*, 299 N.W.2d 414, 419 (Minn.1980); *accord Blaine Econ. Dev. Auth. v. Royal Elec. Co.*, 520 N.W.2d 473, 479 (Minn.Ct.App.1994); *Cashman*, 761 F.2d at 1253;*LeSueur Creamery, Inc. v. Haskon, Inc.*, 660 F.2d 342, 351 (8th Cir.1981).

> FN6. Both sides have applied Minnesota law to the issue of the sufficiency of the evidence on damages, and the Court will therefore do the same. *See Heatherly v. Alexander*, 421 F.3d 638, 641-42 (8th Cir.2005) (applying state law on causation in analyzing a motion for judgment as a matter of law).*But see Finley v. River N. Records, Inc.*, 148 F.3d 913, 918 (8th Cir.1998) (in a diversity case brought under state law, the standard for reviewing whether the evidence was sufficient to support the verdict is set by federal law).

Ordinarily, to recover damages for lost profits, a plaintiff needs to offer evidence defining the market, demonstrating what his share of the market would have been but for the defendant's breach, and establishing the profit he would have earned on the increased sales. At trial, Hinz offered evidence that the market for the use of mucuna pruriens as a treatment for neurotransmitter dysfunction was essentially a two-seller market consisting of Hinz and Kellermann, who competed for the same specialized customer base-and, at least initially, for some of the same customers. To calculate his damages, Hinz offered evidence that the rate of his sales growth fell after Kellermann began breaching the settlement agreement (which, under Hinz's theory, happened immediately after the parties signed it).

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***5** Specifically, Hinz offered evidence that in the year preceding the parties' settlement agreement (August 2002 to September 2003), Hinz's sales grew by 88.2%. Cefalu Aff. Ex. L, Oct. 25, 2006. In contrast, in the three years after the parties entered into the settlement agreement (when Kellermann was continually in breach of it), Hinz's sales grew by only 28.4%, 10.5%, and 18.8%, respectively. *Id.* Because there is no other reason why Hinz's rate of growth would have dropped so substantially, Hinz argues, it is reasonable to assume that Kellermann's breach caused the drop. Further, Hinz contends, in a two-seller market in which his competitor's sales were rapidly increasing, it is reasonable to infer that Hinz's sales would have increased by at least 88.2% per year if Kellermann had not breached the settlement agreement. *See* *B & Y Metal Painting, Inc. v. Ball*, 279 N.W.2d 813, 816 (Minn.1979) (holding that evidence that the plaintiff's growth rate declined while the overall industry grew at a steady pace would tend to prove that the defendant's breaches caused the plaintiff's decline). Hinz argues that a reasonable approximation of his damages can be reached by applying his historical 43% royalty rate to the difference between his actual rate of growth (28.4%, 10.5%, or 18.8%) and his expected rate of growth (88.2%).

The Court has carefully considered the parties' arguments and, although the Court does not doubt that Hinz suffered *some* injury as a result of Kellermann's breach, and although the Court is loathe to overturn the verdict of any jury, the Court cannot help but conclude that Hinz's evidence is too speculative to support an award of damages under Minnesota law. There are several problems with Hinz's evidence.

First, Hinz offered virtually no evidence about his and Kellermann's products, other than that all of the breaching products contain mucuna pruriens and all of them treat neurotransmitter dysfunction. But Hinz and Kellermann sell numerous products containing mucuna pruriens in combination with various other ingredients. These products are used to treat dozens of different conditions and are aimed at very different groups of consumers. Hinz testified that his products are effective in treating obesity, insomnia, pre-menstrual syndrome, depression, and restless leg syndrome, among other conditions. Hinz lumps together all products containing mucuna pruriens in order to compare his sales with Kellermann's sales, but Hinz offered no evidence explaining the difference between the products or why a customer would buy one over another.

Second, because Hinz made no effort to segment the market, he also made no effort to prove which segments of the market were growing and at what rates. There was also no evidence to indicate whether Hinz's sales growth came from new customers or increased sales to existing customers-an important point, since Hinz's chief piece of evidence that Kellermann's breach depressed Hinz's sales was that Kellermann initially marketed his products to Hinz's customers.

***6** Third, Hinz's reliance on only one year's worth of sales growth as a benchmark-his assumption that, because during one year his sales grew by 88.2%, his sales would have continued to grow by 88.2%-is extremely problematic. Hinz offered no evidence whatsoever about whether this one-year increase in sales was aberrational or typical. Nor did Hinz offer any evidence, expert or otherwise, about overall sales growth in the industry-an "industry" that, it should be noted, is small and in its infancy and thus presumably subject to wild fluctuations. The fact that Hinz's sales grew 88.2% in a single year gave the jury no basis for concluding whether, in the absence of competition from Kellermann, Hinz's sales in future years would have grown 8.2%, 88.2%, or 882.0%. The jury was left to speculate, and speculation cannot sustain an award of lost profits.

Hinz's use of the 88.2% sales-growth rate has another flaw. Again, Hinz's argument is that, because his sales increased 88.2% from August 2002 to September 2003 (when the settlement agreement with Kellermann was signed), they would have continued to increase by 88.2% if Kellermann had honored the settlement agreement and not sold products containing mucuna pruriens. According to

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Hinz, the fact that his sales-growth rate dropped from 88.2% in 2002-2003 (the year before the settlement agreement was signed) to 28.4% in 2003-2004 (the year after the settlement agreement was signed) was entirely due to the fact that Kellermann was selling products containing mucuna pruriens in violation of the settlement agreement.

The problem with this reasoning is that, during *both* the "benchmark" year (2002-2003) *and* the three "damages" years (2003-2006), Kellermann was selling products containing mucuna pruriens. Hinz and Kellermann originally planned to be in business together. After their relationship deteriorated, they each went their separate ways, but both continued to sell products containing mucuna pruriens. In September 2003, Hinz and Kellermann signed the settlement agreement, but, from the outset, Kellermann did not interpret the settlement agreement as restricting his ability to sell products containing mucuna pruriens. To this day, Kellermann has not stopped selling products containing mucuna pruriens.

Had Kellermann not been selling products containing mucuna pruriens before the settlement agreement was signed, and then begun selling the products after the settlement agreement was signed, then it would make sense to attribute the drop in Hinz's sales-growth rate to Kellermann. Something would have changed, and that "something" would most likely have been Kellermann. But that's not what happened. Before the settlement agreement was signed, both Hinz and Kellermann were selling products containing mucuna pruriens. After the settlement agreement was signed, both Hinz and Kellermann continued to sell products containing mucuna pruriens. The "something" that changed from the year before the settlement agreement was signed (when Hinz's sales-growth rate was 88.2%) to the year after the settlement agreement was signed (when Hinz's sales-growth rate was 28.4%) was obviously not Kellermann. Hinz's sales must have dropped for some other reason-a reason not even hinted at, much less quantified, by the evidence presented at trial.

***7** This is not to deny that Kellermann's continued presence in the market cost Hinz some sales. Without question, Hinz would have sold more products containing mucuna pruriens had he been able to sell in a one-seller market, instead of competing against Kellermann in a two-seller market. But the jury had no basis whatsoever for figuring out *how many* more products Hinz would have sold. Hinz's theory-that *all* of the drop in his sales-growth rate from 88.2% to 28.4% (and then to 10.5% and 18.8%) was caused by Kellermann's continued presence in the market-simply makes no sense.

With only a rudimentary outline of the relevant market, one year's worth of sales growth at a particular rate, and no evidence that Kellermann's breach actually altered the competitive conditions of the market, Hinz has provided no reasonable basis for the calculation of his damages. Kellermann's motion for judgment as a matter of law is therefore granted with respect to the issue of damages. In light of the Court's disposition of this motion, Kellermann's motion for stay of judgment and Hinz's motion for pre- and post-judgment interest are both denied as moot.

4. Interpretation of the Settlement Agreement

The remainder of Kellermann's motion is based on his argument that there is insufficient evidence to support Hinz's interpretation of the settlement agreement. Kellermann did not properly preserve this argument, because he failed to make it as part of his Rule 50(a) motion. *See Andreas*, 336 F.3d at 794. Instead, Kellermann's Rule 50(a) argument was that the Court erred in finding that the settlement agreement was ambiguous and therefore erred in permitting the jury to consider parol evidence. *See* Trial Tr. vol. III, 488-89, Oct. 6, 2006. This is not the same as arguing that the parol evidence was insufficient to support the jury's verdict as to liability. Kellermann's motion on the issue of the meaning of the settlement agreement is therefore denied.

To the extent that Kellermann's motion rests on his properly preserved argument-that the Court erred in

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permitting the jury to consider parol evidence-the motion is denied for the reasons stated at the February 20, 2007 hearing. The Court continues to believe that the settlement agreement was ambiguous, that parol evidence was admissible on the question of its meaning, and that the jury's verdict regarding the meaning of the agreement was supported by the evidence.

5. Federal Rule of Civil Procedure 50(c)

When a court grants a Rule 50(b) motion, it must also rule in the alternative on a motion for a new trial, if one was brought. *See*Fed.R.Civ.P. 50(c). As explained above, Kellermann's Rule 59(a) motion is not properly before the Court, and the Court therefore need not rule on it under Rule 50(c).

B. Hinz's Motion for a Permanent Injunction

Hinz moves for an injunction permanently prohibiting Kellermann from promoting, marketing, using, or selling any product containing mucuna pruriens. In this diversity action, the Court applies Minnesota law to determine whether a permanent injunction is appropriate. *See Kelly v. Golden*, 352 F.3d 344, 353 (8th Cir.2003); 19 Charles Alan Wright et al., *Federal Practice & Procedure* § 4513 (2d ed.1996).

***8** In Minnesota, a party seeking an injunction must establish that it has no adequate legal remedy and that an injunction is necessary to prevent great and irreparable harm. *Cherne Indus., Inc. v. Grounds & Assocs., Inc.*, 278 N.W.2d 81, 92 (Minn.1979); *Jackel v.. Brower*, 668 N.W.2d 685, 688 (Minn.Ct.App.2003). In this case, although Hinz offered sufficient proof that Kellermann breached the settlement agreement, Hinz has failed to provide a reasonable basis for calculating his damages. This failure also precludes the Court from granting Hinz's requested equitable relief.

To be irreparable, the harm must be of such a nature that money alone cannot remedy it. *See Morse v. City of Waterville*, 458 N.W.2d 728, 729-30 (Minn.Ct.App.1990). The only injury Hinz has identified in this action is lost profits, which are obviously compensable with money damages. Hinz has not shown that he has suffered, or will suffer, any other type of injury. The Court is therefore unable to say that any harm Hinz may be suffering is irreparable.

This case is not like a typical non-compete or trade-secret case in which, absent specific performance, the plaintiff's business is likely to suffer an impairment of goodwill or some other intangible, protectable interest. *Cf. Cherne*, 278 N.W.2d at 94 (affirming injunction against use of confidential information); *Chesney v. Hypertension Diagnostics, Inc.*, No. A05-2210, 2006 WL 2256590, at *6 (Minn.Ct.App. Aug. 8, 2006) (affirming injunction against use of the plaintiffs' names in corporate communications where such use threatened fundamental harm to the plaintiffs' reputations). Nothing in the settlement agreement prevents Kellermann from competing with Hinz for the same customers or in the same territory, and Hinz himself argues that Kellermann is free to use other, equally effective ingredients. If that is the case, there is no basis to infer that Hinz will suffer irreparable harm in the absence of an injunction. Without any showing of irreparable harm, Hinz's motion for an injunction must be denied.

C. Attorney's Fees and Costs

Hinz moves for attorney's fees and costs under ¶ 2 of the settlement agreement, which states as follows:

To the extent it becomes necessary for [Hinz], or any entity substantially owned or controlled by [Hinz], to seek Court enforcement of this provision of the Agreement, and [Hinz] prevails, [Kellermann] agrees to pay all attorneys fees and all costs necessarily incurred by [Hinz] in enforcing this provision[.]

Cefalu Aff. Ex. A at 4, Oct. 25, 2006. The “provision of the Agreement” to which this language refers is the section in which Kellermann agreed to permanently discontinue the promotion, sale, and use of certain specified trade names, trademarks, and products, including, as the jury found, any products containing mucuna pruriens.

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Although this case originally involved multiple claims and counterclaims, the only claim that went to trial was Hinz's claim that Kellermann breached the settlement agreement by selling products containing mucuna pruriens. As Kellermann concedes, the settlement agreement grants Hinz the right to recover all fees and costs "necessarily incurred" in prosecuting that claim. *See* *Schwickert, Inc. v. Winnebago Seniors, Ltd.*, 680 N.W.2d 79, 87 (Minn.2004) (recovery of attorney's fees must be based either on a statute or a contract). The settlement agreement also requires, however, that Hinz *prevail* before he can recover his fees and costs. In light of the pendency of Kellermann's motion for judgment as a matter of law, the Court asked the parties to brief the issue of whether Hinz would be entitled to recover fees and costs even if he did not recover any damages.

***9** Having considered the parties' arguments, the Court reluctantly concludes that Hinz is not entitled to recover attorney's fees and costs under the settlement agreement. As explained above, Hinz has failed to provide sufficient evidence to support an award of damages or the entry of a permanent injunction. Hinz's failure to prove that he is entitled to damages means that his breach-of-contract claim fails as a matter of law. *See* *Jensen v. Duluth Area YMCA*, 688 N.W.2d 574, 578-79 (Minn.Ct.App.2004) ("A breach of contract claim fails as a matter of law if the plaintiff cannot establish that he or she has been damaged by the alleged breach.")

The only manner in which Hinz can be said to have prevailed is that he obtained a jury finding interpreting the settlement agreement in his favor. But Hinz did not seek declaratory relief defining the meaning of the settlement agreement; he sought damages, which he did not recover. While Hinz argues that, at a minimum, he can now take advantage of the preclusive effect of the jury's finding of liability, that is not at all clear. To be given preclusive effect in later litigation, a finding must have been "necessary and essential to the resulting judgment."*See* *Conwed Corp. v. Union Carbide Corp.*, 443 F.3d 1032, 1038 (8th Cir.2006) (applying Minnesota law). Because a failure to prove damages defeats Hinz's claim as a matter of law, *see* *Jensen*, 688 N.W.2d at 578-79, the judgment in this case will provide that Hinz take nothing. The jury's finding of liability cannot be said to be necessary and essential to such a judgment.

To argue otherwise, Hinz points to a quote from a concurrence in *Buckhannon Board and Care Home, Inc. v. West Virginia Department of Health and Human Resources*, 532 U.S. 598 (2001), in which Justice Scalia said: "['Prevailing party'] has traditionally-and to my knowledge, prior to enactment of the first of the statutes at issue here, *invariably*-meant the party that wins the suit or obtains a finding (or an admission) of liability."*Id.* at 616.Hinz contends that he has "obtain[ed] a finding of liability" and therefore has prevailed.

But Justice Scalia wrote this in the context of rejecting the "catalyst" theory for recovery of attorney's fees in civil-rights cases-the theory that, if the plaintiff's lawsuit prompts the defendant to voluntarily cease its allegedly illegal conduct, the plaintiff ought to recover attorney's fees. Justice Scalia was not distinguishing between liability and damages. On that subject, the Supreme Court has said that, when a plaintiff recovers only nominal damages, a reasonable attorney's fee will normally be no fee at all. *See* *Farrar v. Hobby*, 506 U.S. 103, 115 (1992). Similarly, the Supreme Court has held that an appellate court's finding of a constitutional violation did not entitle a plaintiff to recover fees when the plaintiff failed to take the steps necessary to obtain a declaratory judgment, or any other relief, from the district court. *See* *Hewitt v. Helms*, 482 U.S. 755, 760 (1987). As the *Hewiit* Court aptly stated, "Respect for ordinary language requires that a plaintiff receive at least some relief on the merits of his claim before he can be said to prevail."*Id.* Here, Hinz has not obtained any relief on the merits of his claim. The Court therefore concludes that Hinz has not "prevail[ed]" within the meaning of the settlement agreement, and his motion for attorney's fees is therefore denied.

ORDER

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***10** Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Defendants' motions for judgment as a matter of law, or, in the alternative, a new trial [Docket No. 411] are GRANTED in part and DENIED in part as follows:

a. The motion for judgment as a matter of law is GRANTED with respect to the issue of damages.

b. The motions are DENIED in all other respects.

2. Defendants' motion to stay the judgment [Docket No. 413] is DENIED as moot.

3. Plaintiffs' motion [Docket No. 420] is DENIED to the extent that it seeks a permanent injunction and DENIED as moot to the extent it seeks pre- and post-judgment interest.

4. Defendants' motion to stay permanent injunction [Docket No. 434] is DENIED as moot.

5. Defendants' motion to extend time to file notice of appeal [Docket No. 443] is DENIED as moot.

6. Plaintiffs' motion for attorney's fees and costs [Docket No. 459] is DENIED.

7. The judgment entered on October 11, 2006 [Docket No. 395] is VACATED, and a new judgment shall be entered as follows: Plaintiffs shall take nothing from defendants.

LET JUDGMENT BE ENTERED ACCORDINGLY.

D.Minn.,2007.
Hinz v. Neuroscience, Inc.
Slip Copy, 2007 WL 1576116 (D.Minn.)

END OF DOCUMENT

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Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

DePuy Mitek's Memorandum in Support of Its Motion for Summary Judgment of Infringement & Opposing Arthrex's Motion for Summary Judgment of Noninfringement

> handleability without significantly sacrificing the physical properties of the constituent elements of the suture"

(Ex. 1 at 18-19).

2. As a Matter of Law, FiberWire's Surface Coating Does Not Materially Affect Basic and Novel Properties

As the Court recognized in its Order, in attempting to improve suture properties, the prior art had overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability (*id.* at 17). Prior art methods frequently attempted to improve suture properties by using coatings which significantly restricted the movement of adjacent filaments of the braid (*id.*). As explained above, the benefits of the invention claimed in the 446 Patent are realized by mechanically blending dissimilar yarns in direct intertwining contact (Ex. 2 at 2:32-37; 2:49-66; 3:40-51; 8:50-61). But the 446 Patent also teaches that, once those advantageous suture properties are realized by the formation of the heterogeneous braid, they can be *further enhanced* by applying a surface coating to the suture (*id.* at 6:5-21). The 446 Patent therefore "directly speaks to and conclusively answers the question of what constitutes a material effect," as the Court noted in its Order a patent can do (Ex. 1 at 14). The Patent directly states that surface coatings which further enhance properties are contemplated by the invention. Since it is undisputed that FiberWire's coating is a surface coating (it does not substantially penetrate the braid interstices, does not materially affect "fiber mobility," "movement of adjacent filaments," the dissimilar yarn fibers, direct intertwining contact, or the resulting suture properties) (Ex. 6 at ¶¶44; 47; 53; 62-64)), this Court can and should rule, as a matter of law, that FiberWire's silicone coating does not materially affect the basic and novel properties of the suture.

Trying to avoid summary judgment, Arthrex incorrectly tries to spin a single sentence from column 6, lines 13-17 of the 446 Patent as "criticizing" the use of coatings and stating that it is "best to 'avoid'" coatings. But the 446 Patent says neither thing. Rather, it merely states

that, in certain limited circumstances where the amount of lubricous yarn in the suture is significant enough, a "conventional coating *may* be eliminated" saving expense and avoiding potential stiffening (Ex. 2 at 6:16-17) (emphasis added). "May" does not equal "criticize" or "best." Consistent with the remainder of the 446 Patent disclosure, the use of the term "may" indicates that the coating is optional or immaterial.[5]

Arthrex tries to suggest that the Court adopted Arthrex's construction, and that Mitek's counsel admitted that there would be issues of fact precluding summary judgment of infringement if Mitek's construction were not adopted. But the Court did not adopt Arthrex's construction in total, and therefore based on the Court's construction and its statement of the law of materiality, the Court can decide Mitek's motion as a matter of law (Ex. 1 at 14, citing *AK Steel*, 344 F.3d at 1240).[6]

Arthrex cites *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F. 3d 1239 (Fed. Cir. 2001), for the proposition that materials disclosed in the patent and not recited in the claims can materially alter the basic and novel properties of the invention. The case, however, does not stand for that broad proposition. The patent asserted in *AFG Indus.* disclosed that the unlisted ingredient, an interlayer, did not have a material affect if it improved adhesion but did not

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[5] Arthrex incorrectly contends that the 446 Patent criticizes FiberWire's coating because it is supposedly a "thermoset" and the 446 Patent supposedly criticizes all thermoset coatings. But Arthrex's cited "evidence" does not even mention "thermoset" (Arthrex Ex. 24), and there is no evidence defining a "thermoset." Further, the 446 Patent does not "criticize" all thermoset coatings. Rather, it refers to a "particular" PTFE thermoset coating that has a "tendency to flake off during use" (Ex. 2 at 1:48-53). FiberWire's coating is indisputably not PTFE.

[6] *See also PPG Indus. v. Guardian Indus. Corp.*, 156 F. 3d 1351, 1356-57 (Fed. Cir. 1998) (considering patent specification and prosecution history in considering whether effects are material); *Ex parte Boukidis*, 154 U.S.P.Q. 444, 444 (B.P.A.I. 1966) (finding that the expression "consisting essentially of" does not exclude ingredients from the scope of the claims when the specification clearly indicates that other ingredients may be present); *Bayer AG v. Sony Elecs., Inc.*, 229 F. Supp. 2d 332, 343-344 (D. Del. 2002) (considered intrinsic record to determine whether it defined what was per se a material effect); *BASF Corp. v. Eastman Chem. Co.*, No. 95-746-RRM, 1998 U.S. Dist. LEXIS 23054, *28-30 (D. Del. Mar. 24, 1998) (Ex. 18).

substantially affect the optical properties. *Id.* at 1242. The Federal Circuit specifically adopted this standard as the materiality standard. *Id.* at 1252. Because the materiality standard matched the disclosure, if the unlisted ingredient, the interlayer, satisfied the materiality standard, then it also was disclosed as being part of the invention. Thus, *AFG Indus.* actually supports Mitek's position that the Court should adopt the materiality standard defined in the 446 Patent.

Arthrex now alleges that the 446 Patent's prosecution history indicates that the "consisting essentially of" language excludes all coatings. An examination of the prosecution history (Ex. 19) shows that the addition of "consisting essentially of" to the claims had nothing to do with coatings. As Mitek explained in its *Markman* briefing, the "consisting essentially of" language was added to the claims to exclude certain bioabsorbable yarns. Ironically, in response, Arthrex argued that "The Reasons for Adding 'Consisting Essentially of to the Claims [sic] *Has No Impact* On Whether An Unrecited Ingredient *Materially Affects* the Novel and Basic Characteristics" (D.I. 55 at 5) (emphasis added), and the Court addressed the reasons for adding the "consisting essentially of" language separate from defining the novel and basic characteristics (Ex. 1 at 16). Arthrex's position now, that the prosecution history somehow shows that the "consisting essentially of" language excludes coatings, is inconsistent with its prior position.

In summary, even accepting as true Arthrex's factual allegations that FiberWire's surface coating improves knot-tying and handleability, summary judgment of infringement is warranted as a matter of law because the 446 Patent explicitly contemplates such coatings.

3. Arthrex's Tipping Allegations Are Legally Erroneous

Although it is not clear if Arthrex is maintaining this argument, it had previously made an additional "consisting essentially of" argument, alleging that FiberWire does not infringe because about one inch of both ends of the about 38 or 18 inch long FiberWire sutures (Ex. 13 at

Exhibit 6

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., Plaintiff,	)	
v.	)	CIVIL ACTION NO. 04-12457-PBS
ARTHREX, INC. and PEARSALLS LTD. Defendants.	)	

MEMORANDUM AND ORDER

January 31, 2007

Saris, U.S.D.J.

INTRODUCTION

Plaintiff DePuy Mitek, which specializes in the manufacture of surgical devices, alleges that Arthrex, Inc., and Pearsalls Ltd. (collectively "Arthrex"), two of Plaintiff's competitors, have infringed U.S. Patent No. 5,314,446 ("the '446 Patent"). Broadly, the '446 patent protects a braided surgical suture with two multi-filament yarns made from different materials. Beyond this definition, though, the parties disagree as to two key terms in the '446 Patent.

DePuy Mitek and Arthrex have moved for summary judgment on the issue of infringement. After a Markman hearing, the Court defines the two contested patent terms and **DENIES** without prejudice Plaintiff's motion for summary judgment of infringement and Defendants' motion for summary judgment of noninfringement.

at 1240. Where the specification and/or prosecution history directly speaks to and conclusively answers the question of what constitutes a material effect, the issue may be resolved as a question of law. Id. In some situations, however, whether an additional ingredient materially affects the basic and novel characteristics of a patented invention is a question of fact for a jury. See PPG, 156 F.3d at 1357 (stating that it is the province of the jury to determine whether the iron sulfide had a material affect on the basic and novel characteristics of the patented glass).

The key question of claim construction for this term in Claim One involves discerning the basic and novel properties of the heterogeneous suture. Once this determination has been made, the Court can attempt to resolve the parties' disagreement over whether the surgical coating placed on FiberWire braided suture "materially affects" the basic and novel properties of the suture described by the '446 Patent. AK Steel, 344 F.3d at 1239.

The Defendants submit that this Court should construe the claim term "consisting essentially of" as follows:

> i) The claimed surgical suture excludes additional ingredients that materially affect the basic and novel characteristics of the claimed invention.
>
> ii) The basic and novel characteristics of the claimed invention are a suture having two dissimilar yarns (from the list identified in the claims) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties.

added). Later, the applicant again distinguishes the prior art: "Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e., PTFE) and a second set of nonabsorbable yarn (i.e., PET). (DM 1000260).[4] Id. Thus the Plaintiff argues there is a clear and express disclaimer of bioabsorbable yarns in the prosecution history. SanDisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1286 (Fed. Cir. 2005).

Defendants contend that the prosecution history does not support this interpretation because the patent specification provides, "The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired." '446 Patent col.3 ll.63-65 (emphasis added). Still, under the doctrine of prosecution disclaimer, Plaintiff's argument that it clearly disclaimed bioabsorbable yarns to overcome the rejection seems persuasive. Nonetheless, this debate seems largely beside the point because the issue here involves coatings, not bioabsorbable yarns.

The Defendants contend that the invention's primary basic and novel characteristic is that it improves the handleability and pliability of a suture without significantly sacrificing any physical properties of the constituent materials of the device, like strength or knot tiedown. The specifications reveal that

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[4]In addition, the plaintiff pointed out that Kaplan taught that sheath yarns listed in the invention should not be used in sheaths.

the mechanical braiding of the two dissimilar fibers was intended to enhance the overall pliability of the device. As the "Background of the Invention" section notes, "the enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament." '446 Patent col.1 ll.12-15. For this reason, the inventors eschewed "any mechanism which reduces this individual fiber mobility." Id. at col.1 ll.18-19. The specification states that the invention relates to "sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures." Id. at col. 1 ll. 6-8. These "[b]raided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts." Id. at col.1 ll.8-10. The specification points out, "Unfortunately, the prior art abounds with attempts to improve specific properties of multi-filament braids at the expense of restricting the movement of adjacent filaments which make up the braid. For example, multi-filament sutures almost universally possess a surface coating to improve handling properties." Id. at col. 1 ll. 26-31. It continues: "All of the attempts described in the prior art have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability." Id. at col. 2 ll. 14-17. Of significance, the specification states:

> In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties."

Id. at col.2 ll, 32-37 (Emphasis added).

Plaintiff argues that increased pliability is a property only of the preferred embodiment, pointing to the passage that states: "For example, in preferred embodiments, the heterogenous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security." Id. at col. 2 ll. 50-67. As shown above, this is a myopic view of the specification, which states throughout that a primary goal of the invention is to achieve enhanced pliability and handleability. The sterilized heterogeneous braids described in this patent seek to achieve a high degree of pliability and handleability by mechanically blending together two dissimilar synthetic yarns.

Therefore, this Court concludes that the basic and novel properties of the suture described in the '446 Patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and handleability

without significantly sacrificing the physical properties of the constituent elements of the suture.

2. Summary Judgment

As noted previously, both DePuy Mitek and Arthrex have moved for summary judgment on the issue of patent infringement. However, the summary judgment record is a mess because of the multiple motions to strike, each with extensive appendices and confusing briefing. This Court has allowed Arthrex to supplement Dr. Gitis's expert report to correct certain typographical and computational errors. Moreover, DePuy Mitek has launched a Daubert challenge to Defendants' expert report, and it is difficult to figure out the various expert opinions on the affect of the coatings on the accused devices. Accordingly, this Court will deny these cross-motions for summary judgment without prejudice.

ORDER

Plaintiff's motion for summary judgment of infringement is **DENIED** without prejudice (Docket No. 36). Defendants' motion for summary judgment of noninfringement is **DENIED** without prejudice (Docket No. 39).

All parties are ordered to submit a single brief, not to exceed 20 pages, on the summary judgment issue of patent infringement within 60 days in light of the Court's construction of the '446 Patent. The parties shall file no additional motions

Exhibit 7

US005314446A

United States Patent [19]

Hunter et al.

[11] Patent Number: 5,314,446

[45] Date of Patent: May 24, 1994

[54] **STERILIZED HETEROGENEOUS BRAIDS**

[75] Inventors: Alastair W. Hunter, Bridgewater; Arthur Taylor, Jr., Plainfield, both of N.J.; Mark Steckel, Maineville, Ohio

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[21] Appl. No.: 838,511

[22] Filed: Feb. 19, 1992

[51] Int. Cl.[5] D04C 1/00

[52] U.S. Cl. 606/231; 606/228; 87/7; 87/9; 428/370

[58] Field of Search 606/228, 230, 231; 87/7, 8, 9; 428/225

[56] References Cited

U.S. PATENT DOCUMENTS

3,187,752	6/1965	Glick	128/335.5
3,463,158	8/1969	Schmitt et al.	606/228
3,527,650	9/1970	Block	117/7
3,636,956	1/1972	Schneider	128/335.5
3,942,532	3/1976	Hunter et al.	128/335.5
4,043,344	8/1977	Landi et al.	128/335.5
4,047,533	8/1977	Perciaccante et al.	128/335.5
4,052,988	10/1977	Doddi et al.	128/335.5
4,141,087	2/1979	Shalaby et al.	3/1
4,470,941	9/1984	Kurtz	264/136
4,624,256	11/1986	Messier et al.	128/335.5
4,946,467	8/1990	Ohi et al.	606/228
4,959,069	9/1990	Brennan et al.	606/228
4,979,956	12/1990	Silverstrini	623/13
5,116,360	5/1992	Pinchuk et al.	623/1
5,147,400	9/1992	Kaplan et al.	623/13

FOREIGN PATENT DOCUMENTS

2949920	3/1981	Fed. Rep. of Germany	A61F 1/00
WO86/00020	1/1986	PCT Int'l Appl.	A61L 17/00
2082213	8/1980	United Kingdom .	
2218312A	11/1989	United Kingdom	A01K 91/00

Primary Examiner—George F. Lesmes
Assistant Examiner—Chris Raimund
Attorney, Agent, or Firm—Hal Brent Woodrow

[57] **ABSTRACT**

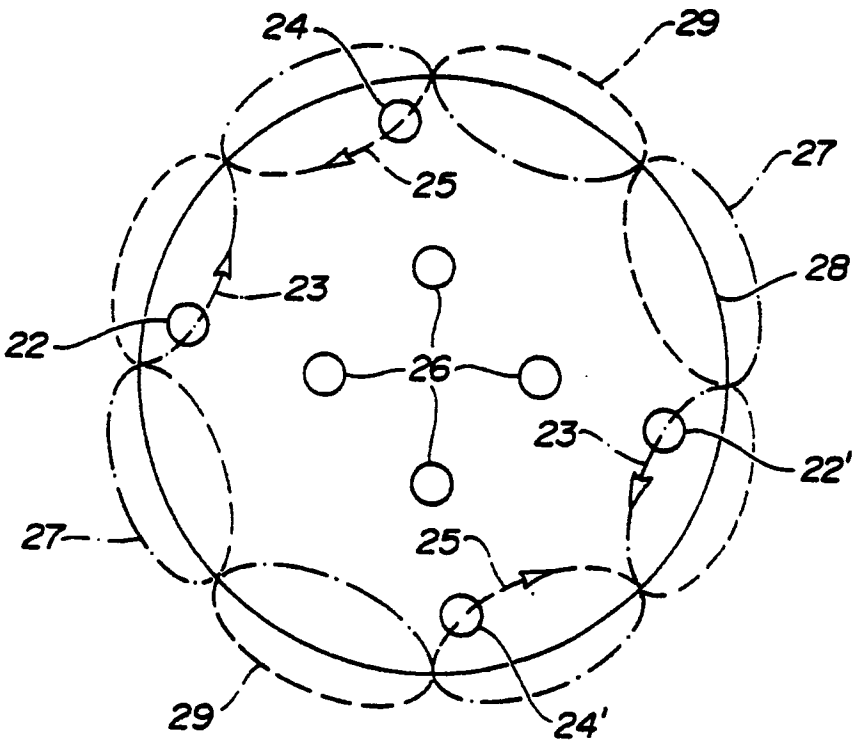
Heterogeneous braided multifilament of first and second set of yarns mechanically blended by braiding, in which first and second set of yarns are composed of different fiber-forming materials.

Heterogeneous braids are useful for preparation of surgical sutures and ligatures.

12 Claims, 3 Drawing Sheets

DEPUY MITEK
EXHIBIT 130
04cv12457
12-6-05

FIG-1



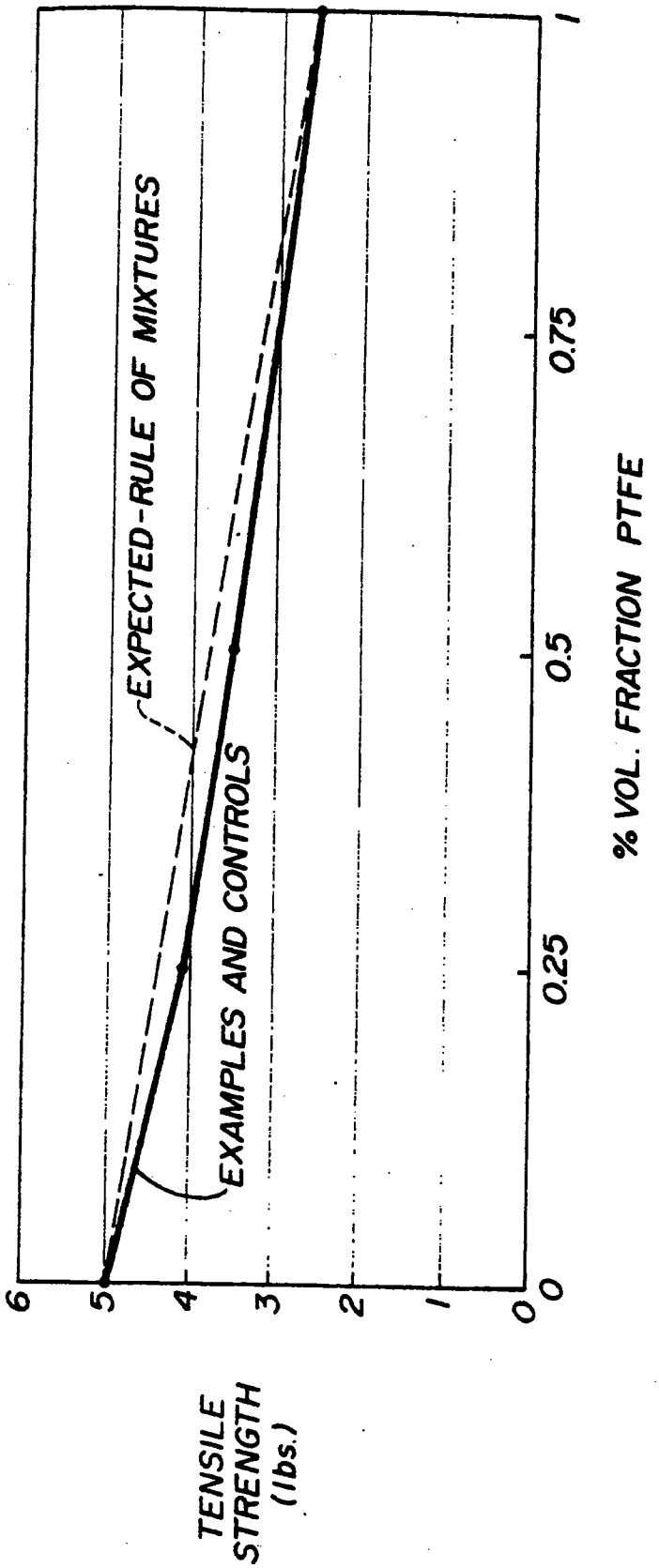
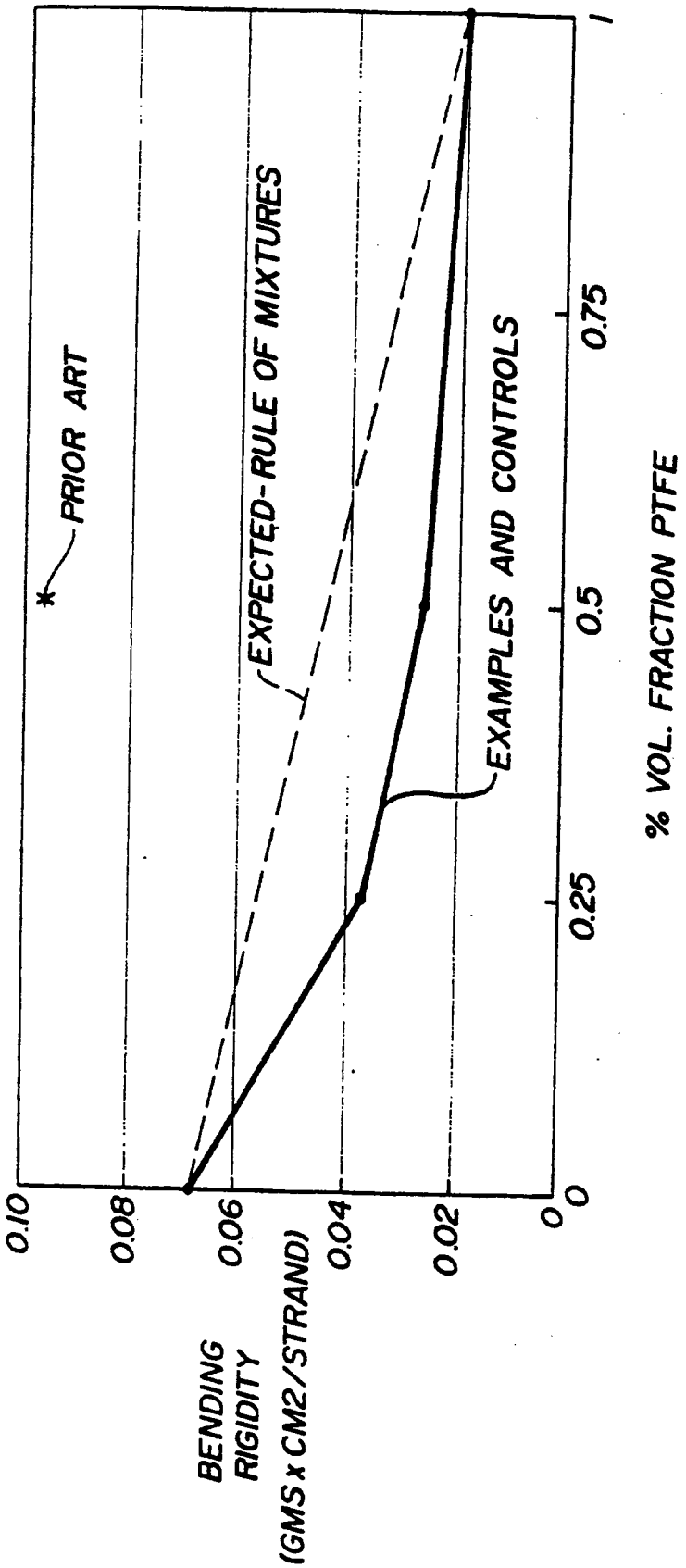

EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
TENSILE STRENGTH (lbs.)
6
5
4
3
2
1
0
0
0.25
0.5
0.75
1
% VOL. FRACTION PTFE

FIG-2

FIG-3


PRIOR ART
EXPECTED-RULE OF MIXTURES
EXAMPLES AND CONTROLS
0.10
0.08
0.06
0.04
0.02
0
0
0.25
0.5
0.75
1
BENDING RIGIDITY (GMS x CM2/STRAND)
% VOL. FRACTION PTFE

STERILIZED HETEROGENEOUS BRAIDS

BACKGROUND OF THE INVENTION

This invention relates to braided multifilaments, and especially to sterilized, braided multifilaments suitably adapted for use as surgical sutures or ligatures.

Braided multifilaments often offer a combination of enhanced pliability, knot security and tensile strength when compared to their monofilament counterparts. The enhanced pliability of a braided multifilament is a direct consequence of the lower resistance to bending of a bundle of very fine filaments relative to one large diameter monofilament. However, for this enhancement to be realized, the individual multifilaments must be able to bend unencumbered or unrestricted by their neighboring filaments. Any mechanism which reduces this individual fiber mobility, such as simple fiber-fiber friction, a coating which penetrates into the braid interstices, or a melted polymer matrix which adheres fibers together, will adversely affect braid pliability. In the extreme case where the multifilaments are entirely bonded together, the pliability or bending resistance closely approximates that of a monofilament.

Unfortunately, the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid,. For example, multifilament sutures almost universally possess a surface coating to improve handling properties.

U.S. Pat. No. 3,942,532 discloses a polyester coating for multifilament sutures. The preferred polyester coating is polybutilate, which is the condensation product of 1,4-butanediol and adipic acid. U.S. Pat. No. 4,624,256 discloses a suture coating copolymer of at least 90 percent ϵ-caprolactone and a biodegradable monomer, and optionally a lubricating agent. Examples of monomers for biodegradable polymers disclosed include glycolic acid and glycolide, as well as other well known monomers typically used to prepare bioabsorbable coatings for multifilament sutures.

An alternative to the use of the commonly accepted coating compositions for multifilament sutures to improve handling properties is disclosed in U.S. Pat. 3,527,650. This patent discloses a coating composition of polytetrafluoroethylene (PTFE) particles in an acrylic latex. Although the PTFE particles act as an excellent lubricant to decrease the surface roughness of multifilament sutures, the particles have a tendency to flake off during use. Also, this particular coating is a thermoset which requires a curing step for proper application.

More recently, a dramatic attempt has been made to create a monofilament-like surface for a multifilament suture. U.S. Pat. No. 4,470,941 discloses the preparation of "composite" sutures derived from different synthetic polymers. The composite suture is composed of a core of low melting fibers around which are braided high melting fibers. Because of the lack of cohesiveness of the dissimilar fibers, the low melting fibers in the core are melted and redistributed throughout the matrix of the braided, high melting fibers. Although these composite sutures represent an attempt to combine the best properties of different synthetic fibers, it unfortunately fails in this respect due to increased stiffness (as evidenced by FIG. 3 which is described in detail below),

apparently due to the reduction of fiber mobility resulting from the fusing of the fibers together.

Another attempt to enhance the properties of multifilament sutures can be found in WO 86/00020. This application discloses coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier with a film-forming surgical material. The film-forming surgical material can be absorbable or nonabsorbable, and can be coated on the elongated core by solution casting, melt coating or extrusion coating. Such coated multifilament sutures suffer from the same deficiencies which plague conventionally coated multifilament sutures.

All of the attempts described in the prior art to improve braid properties have overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability. The properties of concern here include the fiber-fiber frictional coefficients (which frequently relate to the polymer's surface energy), the fiber cross-sectional shape and diameter, and the braid structure which influences the transverse forces across the braid. If fibers composed of highly lubricous polymers are used in the traditional manner, then a highly pliable braid can be prepared. However, in most cases, these braids will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments.

In view of the deficiencies of the prior art, it would be desirable to prepare multifilament sutures exhibiting improved pliability and handling properties. More specifically, it would be most desirable to prepare braided multifilaments composed of dissimilar fiber-forming materials in which the fiber-forming materials contribute significantly to enhanced pliability for the braided multifilament without appreciably sacrificing its physical properties.

SUMMARY OF THE INVENTION

The invention is a heterogeneous braid comprising a first and second set of continuous and discrete yarns in a sterilized, braided construction. At least one yarn from the first set is in direct intertwining contact with a yarn from the second set.

Each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material, and each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material.

Surprisingly, the heterogeneous braids may exhibit a combination of outstanding properties attributable to the specific properties of the dissimilar fiber-forming materials which make up the braided yarns. The dissimilar fiber forming materials do not require melt bonding or any other special processing techniques to prepare the heterogeneous braids of this invention. Instead, the integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual yarns. In fact, it is possible to tailor the physical and biological properties of the braid by varying the type and proportion of each of the dissimilar fiber forming materials used, as well as adjusting the specific configuration of the braid. For example, in preferred embodiments, the heterogeneous braid will exhibit improved pliability and handling properties relative to that of conventional homogeneous fiber braids, without sacrificing physical strength or knot security.

The sterilized, heterogeneous braids of this invention are useful as surgical sutures or ligatures, as well as for

the preparation of any other medical device which would benefit from its outstanding physical or biological properties.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a carrier layout for the preparation of a heterogeneous braid within the scope of this invention;

FIG. 2 is a plot representing the relationship between the tensile strength of heterogeneous and homogeneous braids of polyethylene terephthalate (PET) and PTFE yarns, and the volume fraction of PTFE yarns in the braids; and

FIG. 3 is a plot representing a relationship between the initial bending rigidity of heterogeneous and homogeneous braids of PET and PTFE yarns, and the volume fraction of PTFE yarns in the braids.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of describing this invention, a "heterogeneous" braid is a configuration composed of at least two sets of dissimilar yarns mechanically blended by intertwining the dissimilar yarns in a braided construction. The yarns are continuous and discrete, so therefore each yarn extends substantially along the entire length of the braid and maintains its individual integrity during braid preparation, processing and use.

The heterogeneous braids of this invention can be conventionally braided in a tubular sheath around a core of longitudinally extending yarns, although such a core may be excluded, if desired. Braided sheath sutures with central cores are shown in U.S. Pat. Nos. 3,187,752; 4,043,344; and 4,047,533, for example. A core may be advantageous because it can provide resistance to flattening, as well as increased strength. Alternatively, the braids of this invention can be woven in a spiral or spiroid braid, or a lattice braid, as described in U.S. Pat. Nos. 4,959,069 and 5,059,213.

The dissimilar yarns of the first and second set of yarns are braided in such a manner that at least one yarn from the first set is directly intertwined with, or entangled about, a yarn from the second set. Direct mechanical blending of individual, dissimilar yarns therefore occurs from the interweaving and interlocking of these dissimilar yarns, enhancing yarn compatibility and the overall physical and biological properties of the heterogeneous braid. Preferably, every yarn from the first set is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar yarns.

The first and second fiber-forming materials which make up the filaments of the first and second set of yarns, respectively, can be any materials capable of being spun into continuous filaments. Advantageously, the fiber-forming materials are nonmetallic.

The preferred fiber-forming materials are synthetic fiber-forming polymers which are melt or solution spun through a spinneret to prepare continuous filaments. The filaments so prepared are advantageously stretched to provide molecular orientation and annealed to enhance dimensional stability and/or biological performance. The fiber-forming polymers can be bioabsorbable or nonabsorbable, depending on the particular application desired. Examples of monomers from which bioabsorbable polymers are derived include, but are not limited to, some hydroxyacids and lactones, e.g. glycolic acid, lactic acid, glycolide, lactide, p-dioxanone, ϵ-caprolactone and trimethylene carbonate, as well as copolymers and polymer blends derived from these monomers and others. Interestingly, numerous bioabsorbable heterogeneous braids exhibiting varying useful biological properties, such as breaking strength retention in vivo and the absorption profiles in vivo, can be prepared for specific applications by using different combinations of bioabsorbable polymers.

Preferably, the continuous filaments which make up the first and second set of yarns are derived from nonabsorbable polymers. In a preferred embodiment, the first set of yarns acts as lubricating yarns to improve the overall pliability, or compliance, and surface lubricity of the heterogeneous braid. Preferably, the fiber-forming material of the first set exhibits a surface energy (which frequently relates to surface lubricity) less than about 38 dyne/cm, as measured by contact angle of liquids on polymer surfaces, as described by Kissa, E., "Handbook of Fiber Science and Technology," Vol. II, Part B, Marcel Decker, 1984. Such fiber forming polymers include perfluorinated polymers, e.g. PTFE and fluorinated ethylene/propylene copolymers (FEP) and perfluoroalkoxy (PFA) polymers, as well as non-perfluorinated polymers such as polyvinylidene fluoride (PVDF), polyethylene/tetrafluorethylene copolymers (PETFE), the polycholorofluoroethylene polymers, polypropylene (PP) and polyethylene (PE). More preferably, the first fiber-forming material exhibits a surface energy less than about 30 dyne/cm. The preferred polymers for the first set are PTFE, PETFE, FEP, PE and PP, and the most preferred fiber forming polymer is PTFE.

In a more preferred embodiment, the lubricating yarns of the first set are mechanically blended with yarns of the second set which act to provide improved strength to the heterogeneous braid. Preferably, the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier, more preferably greater than 5.0 grams denier. The preferred yarns are PET, nylon and aramid, and the most preferred yarns are PET.

In the most preferred embodiment, the heterogeneous braid is composed of a first set of PTFE yarns mechanically blended with a second set of PET yarns in a braided configuration. Advantageously, the braided sheath encloses a core of longitudinally extending PET yarns to further improve the overall strength and resistance to flattening of the heterogeneous braid. In this embodiment, the volume fraction of lubricating yarns in the braided sheath and core desirably ranges from about 20 to about 80 percent. A volume fraction of lubricating yarns below about 20 percent will not typically improve the pliability of the braid, and a volume fraction above about 80 percent may adversely affect the overall strength of the braid. The filament fineness for such a heterogeneous braid is preferably less than 10 denier per filament, preferably from about 0.5 to about 5 denier per filament. A more coarse filament may result in a stiffer braid. The preferred individual yarn denier is between 10 and 100 denier.

The heterogeneous braids of this invention can be prepared using conventional braiding technology and equipment commonly used in the textile industry, and in the medical industry for preparing multifilament sutures. For example, the first and second set of yarns can be interwoven as indicated by the plan view of the yarn carrier layout of FIG. 1 for the preparation of a braided multifilament. The individual yarns of the braided sheath feed from spools mounted on carriers 22, 22' and

24, 24'. The carriers move around the closed circular loop 28, moving alternately inside and outside the loop 28 to form the braiding pattern. One or more carriers are continually following a serpentine path in a first direction around the loop, while the remaining carriers are following a serpentine path in the other direction.

In the illustrated embodiment, carriers 22, 22' are travelling around serpentine path 27 in a clockwise direction as indicated by directional arrows 23, and carriers 24, 24' are travelling around serpentine path 29 in a counterclockwise direction as indicated by arrows 25. The moving carriers dispense yarns which intertwine to form the braid. The yarns from all the carriers in a constructed embodiment of FIG. 1 are dispensed upward with respect to the plane of the drawing, and the braid is taken up on a reel located above the plane of the drawing.

In one embodiment, moving carriers 22, 24 dispense yarns of the first set and moving carriers 22', 24' dispense yarns of the second set to form the heterogeneous braid. In a more preferred embodiment, moving carriers 22, 22' dispense yarns of the first set and moving carriers 24, 24' dispense yarns of the second set. This carrier layout provides a braid in which each yarn of the first set is directly intertwined with a yarn from the second set.

Advantageously, as illustrated in FIG. 1, disposed within the center of the loop 28 are carriers 26 which dispense the core yarns of the braid. In the most preferred embodiment of this invention, moving carriers 22, 22' dispense PTFE yarns, moving carriers 24, 24' dispense PET yarns, and core carriers 26 dispense PET yarns.

Numerous additional embodiments are contemplated within the scope of the invention using conventional braiding technology and equipment. For example, the carrier layout can be modified to prepare a braid configuration using from 3 to 28 sheath carriers, with or without any number of core yarns. Dissimilar yarns from the first and second set of yarns can be plied together using conventional techniques before braiding, and in this embodiment, the carriers can dispense identical bobbins of plied yarns composed of individual yarns from the first and second sets. This embodiment not only offers the advantage of inter-yarn mechanical blending, but also the intimate mixing associated with intra-yarn blending.

Similar to the preparation of conventional homogeneous braids, the yarns from which the heterogeneous braids are prepared are preferably nontextured. The yarn tension during braiding is advantageously adjusted so that the yarn elongation for each set of yarns is about equal. The equilibration of yarn elongation may prevent irregularities, for example, "core popping", which is the tendency of core yarns to break through the braided sheath as the braid is bent. The number of picks per inch in the finished braid can be adjusted to balance the tensile strength of the braid with braid quality, e.g. the tendency for core popping and overall braid smoothness.

After the heterogeneous braid is prepared, it is desirably scoured to remove machine oils and lubricants, and any foreign particles. The scoured braid is preferably stretched at a temperature between the glass transition temperature and melting temperature of the lower melting set of yarns. Therefore, the stretching temperature is such that none of the yarns is actually melted. The stretching operation densifies the braid and improves braid smoothness. Afterwards, the braid may be annealed while under restraint to improve dimensional stability, and in the case of absorbable braids, to improve the breaking strength retention in vivo.

If desired, the surface of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricous yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the surface of the braid is coated, than the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

The post-treated heterogeneous braid is sterilized so it can be used for a host of medical applications, especially for use as a surgical suture, preferably attached to a needle. The braid can be sterilized using any of the conventional techniques well known in the art. For example, sterilization can be effected by exposing the braid to gamma radiation from a cobalt 60 source. Alternatively, the braid can be sterilized by exposure to ethylene oxide.

In the following examples, the tensile properties and knot security are each determined using an Instron Tensile Tester. The tensile properties, i.e. the straight and knot tensile strength and the percent elongation, are determined generally according to the procedures described in U.S. Pat. No. 4,838,267. The knot security, which provides an indication as to the number of throws required to secure a knot so that it fails to slip before cleanly breaking, is measured by first tieing a conventional square knot around a mandrel, pulling the knot apart on the Instron Tester to observe whether slipping occurs, and if so, then tieing knots with additional throws until 20 out of 20 knots break cleanly without slipping. The bending rigidity, which is the inverse of pliability, is determined using a Kawabata Pure Bending Tester, as discussed in "The Effects of Structure on the Geometric and Bending Properties of Small Diameter Braids", Drexel University Master Thesis, 1991, by Mr. E. Ritter.

The examples are illustrative only, and are not intended to limit the scope of the claimed invention. The types of yarns used to prepare the heterogeneous braid and the yarn geometry can be varied to prepare heterogeneous braids within the scope of the claimed invention which exhibit a combination of outstanding physical or biological properties.

EXAMPLES

Examples I and II describe heterogeneous braids of PTFE and PET yarns. In order to evaluate the relative performance of these braids, two controls are included which represent 100% PET and 100% PTFE braids, respectively. To the extent possible, the yarn materials and processing conditions are identical for the controls and heterogeneous braid examples. In addition, for comparison purposes, a braid is fabricated with identical materials but processed per the prior art U.S. Pat. No. 4,470,941.

CONTROL I

FIBER MATERIALS: An 8×0 PET braid is fabricated, i.e. 8 sheath yarns and 0 core yarns. All yarns are Dupont Dacron PET, 70 denier, 48 filament, type 52 yarn.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 32 pick gear, 0.009" wire tension springs, and 183 rpm. The braid is aqueous scoured, and hot stretched at 30% draw ratio at 225° C.

CONTROL II

FIBER MATERIALS: An 8×0 PTFE braid is fabricated. All yarns are Dupont Teflon, 110 denier, 12 filament.

PROCESSING: The yarns are wound on braider bobbins per conventional methods, and the bobbins loaded on each carrier of a N.E. Butt 8 carrier braider. Machine settings include: 36 pick gear, no tension springs, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE I

FIBER MATERIALS: An 8×0 heterogeneous braid is fabricated, consisting of four PET 70 denier yarns and four PTFE 110 denier yarns. The yarns are identical to that employed in CONTROL I and II. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Four bobbins of PET yarn and four bobbins of PTFE yarn were wound by conventional means. The PET bobbins were loaded on the clockwise moving carriers of the N.E. Butt 8 carrier braider, and the PTFE yarn bobbins on the counter-clockwise moving carriers. Machine settings include: 32 pick gear, 0.009" tension springs on PET carriers, no springs on PTFE carriers, and 183 rpm. The braid is scoured and hot stretched per the conditions described in CONTROL I.

EXAMPLE II

FIBER MATERIALS: Identical to EXAMPLE I, except that 6 PET yarns and 2 PTFE yarns were used. On a volume basis, the braid is 75.5% PET, and 24.5% PTFE.

PROCESSING: Identical to EXAMPLE I, except that 2 PET bobbins replace 2 PTFE bobbins. All other braider machine settings, scour and hot-stretch conditions are identical to CONTROL I and II and EXAMPLE I.

PRIOR ART I

FIBER MATERIALS: Identical to EXAMPLE I. On a volume basis, the braid is 50.3% PET, and 49.7% PTFE.

PROCESSING: Identical to EXAMPLE I, except that the hot stretch temperature is at 300° C. and for a longer residence time to facilitate melting of the PET fibers.

The properties of CONTROLS I and II, and EXAMPLES I and II, and the PRIOR ART I are summarized in the following Table:

	USP DIAMETER (mils)	TENSILE STRENGTH (lbs)	KNOT STRENGTH (lbs)	BENDING RIGIDITY (gm × cm²)	KNOT STABILITY (# of throws)
CONTROL I	10.68	4.98	3.14	0.0680	4
CONTROL II	9.11	2.58	2.04	0.0196	7
EXAMPLE I	9.71	3.55	2.41	0.0257	5
EXAMPLE II	10.35	4.10	2.67	0.0371	5
PRIOR ART I	8.81			0.0966	

As may be expected, the tensile strengths of the heterogenous braid examples reflect the relative contributions of the individual components. This behavior is said to follow the "rule of mixtures", i.e. the composite property is a weighted average of the component properties. In equation form,

$$P_c=(Vf_a)(P_a)+(Vf_b)(P_b)$$

where P_c is a composite property (such as tensile strength or modulus), P_a and P_b are the properties of the components a and b, and Vf_a and Vf_b are the volume fractions of components a and b. This behavior is clearly observed in FIG. 2, which shows a plot of tensile strength versus volume fraction of PTFE yarns for the Examples and Controls, in relation to the expected plot according to the rule of mixtures.

Surprisingly, the bending rigidity of the heterogeneous braids in EXAMPLES I and II do not follow the rule of mixtures, and show an enhanced bending rigidity relative to the weighted average of its components. This is shown in FIG. 3 as a plot of bending rigidity versus %PTFE in the braids. Bending rigidity is the inverse of pliability, and is obtained by measuring the slope of the *bending moment-radius of curvature* plot of a suture strand in pure bending. Hence lower bending rigidity relates to a more pliable suture, which is a highly desirable property. The mechanism of this enhanced pliability is believed to be internal lubrication of the braid by the "solid lubricant" behavior of the low surface energy PTFE.

U.S. Pat. No. 4,470,941 discloses the preparation of a "composite" suture with a monofilament-like surface made from multifilament yarns. The composite suture is composed of two different synthetic polymer fibers, which is thermally processed to melt one of the fibers to form a continuous matrix. This process was utilized to produce the PRIOR ART I example, the data of which is shown in Table 1 and FIG. 3. It is observed that the melting of the PET fibers significantly increases the braid bending rigidity due to the bonding of the "non-melted" fibers together, hence resulting in a less pliable braid of diminished utility.

What is claimed is:

1. A surgical suture consisting essentially of a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

2. The surgical suture of claim 1 wherein the suture is attached to a needle.

3. The surgical suture of claim 1 wherein the first fiber-forming material exhibits a surface energy less than about 38 dynes/cm.

4. The surgical suture of claim 3 wherein the first fiber-forming material exhibits a surface energy less than about 30 dynes/cm.

5. The surgical suture of claim 4 wherein the first set of yarns is PTFE.

6. The surgical suture of claim 5 wherein the second set of yarns exhibits a yarn tenacity greater than 3.0 grams/denier.

7. The surgical suture of claim 6 wherein the second set of yarns exhibits a yarn tenacity greater than 5.0 grams/denier.

8. The surgical suture of claim 1 wherein the second set of yarns is PET.

9. The surgical suture of claim 8 wherein the volume fraction of the first set of yarns in the braided sheath and core ranges from about 20 to about 80 percent.

10. The surgical suture of claim 9 wherein the fiber fineness of the yarns of the first and second sets is less than 10 denier per filament.

11. The surgical suture of claim 1 wherein at least one yarn from the first set of yarns is plied together to a yarn from the second set of yarns.

12. The surgical suture of claim 8 wherein the suture is attached to a needle.

* * * * *

Exhibit 8

BOOK NO. 2175

ETHICON, INC.
a Johnson & Johnson company

Issued to Mark Stickel

Covering the Period

Feb 29, 1988 to

EXHIBIT
DEPUY MITEK
EXHIBIT 520
04cv12457

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Page
Book No. 2175

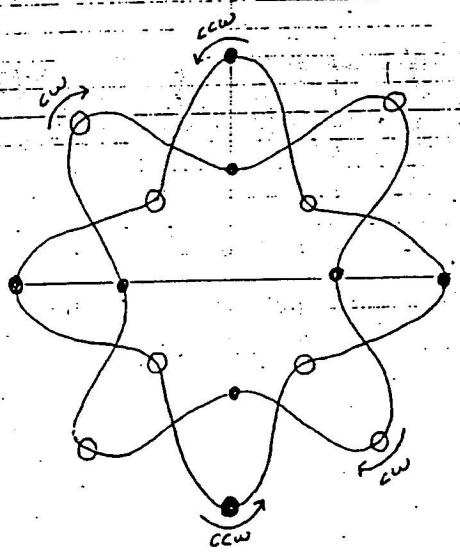
Project No. CBE Experiment No. Date 12/13/89

Subject CONTIN. FROM 2125-56

Purpose

PROPERTIES:

THE DIAMOND COMPOSITE BRAID HAD SUPERIOR HANDLING PROPERTIES RELATIVE TO SILK AND ETHIBOND, WHICH IS DEMONSTRATED QUANTITATIVELY IN FIG 2 OF THE MANUSCRIPT. BENDING RIGIDITY RESULTS. THE INTRINSIC TENSILE AND KNOT STRENGTHS WERE 87 KSI AND 48 KSI RESPECTIVELY. THE COMPOSITE ALSO RANKED BETTER THAN THE SILK AND ETHIBOND IN KNOT TIE-DOWN, EVEN WITHOUT A COATING.



MS 12/13/89

FIG. 1. SCHEMATIC OF CARRIER LAY OUT FOR BALANCED COMPOSITE BRAID.

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DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI002666

Investigator [signature] Date 12/13/89

Witness Crawford Britt Date 3-15-90

Exhibit 9

1

THE CLERK: Members of the jury, please remain standing. Everyone else, you may be seated.

THE COURT: Good afternoon.

THE JURY: Good afternoon.

THE COURT: There's an old traditional in the Federal Courts and in the courts of our Commonwealth that at this stage of the proceedings, the judge stands and faces the jury, and the jury faces the judge. This is the best way that I know how to symbolize the important role that we both play at this trial.

My job has been threefold. The first was to impanel a fair and impartial jury. You heard both sides say, "We're content with this jury," and on behalf of everyone in this room, I thank you for spending the time here in court.

My second job was to rule on the evidentiary objections. We did that before court, while you were here, and after court.

And now my third and final task is to give you the instructions of law. You must follow those instructions whether you agree with them or not. To the extent that I say anything differently from what the attorneys say, you must follow my instructions of law. As I'm sure you will now

agree, though, I have the easy job, and you've got the tough one, because it will be your job to render a unanimous verdict, and I will give you instructions now to tell you the law that applies in rendering your verdict.

2

My instructions will be in three parts. The first part is very general, similar to the instructions I gave you on the first day of this trial: What is evidence? What isn't evidence? What is the burden of proof? The second portion is very specific to the claim in this case, the one I gave you the verdict form on, and I will go through in detail what the plaintiff must prove. My third portion of the instruction is what I call the mechanics of deliberation: How do you choose a foreperson, and how do you go about deliberating?

I want to emphasize that although I look as if I'm reading, I really am reading, and the reason I do is to make sure that I get the law to you as clearly as I can based on the federal statutes that govern patent law as well as based on the case law interpreting that patent law.

You will get a tape recording of my charge, but I will not today give you a written charge. Ms. Marzilli has offered to try and get you a written charge tomorrow, but as I may have said at the start of this trial, we're not like an ATM machine. She doesn't just press a button and a charge doesn't just pop out. So I don't want you to have to wait for deliberations until the written charge is prepared, so what I'm going to be doing is giving you a tape recording of the charge to help you. But I want to emphasize that you should be taking notes about the charge. Why? First,

because it will help you get to the tape recording and get to the portion of the charge that you may need to go through again, and, second, because it's now past 3:30, it's almost quarter to 4:00, and just I want to make sure you don't daydream because it's absolutely essential that you get down what the law is that you must apply in resolving this dispute. So why don't we sit down and get going, all right?

What is my role as the Court? These instructions

are about the law you must apply. I don't mean any of my instructions to be understood by you as a comment by me on the facts or on the evidence of the case. Rather, you're the judges of the facts and the sole judges of the credibility of the witnesses.

I may repeat certain of the instructions. Why? Because I might think one of you looks confused or because I think that it is a difficult concept, but all of the portions of the instruction are equally important. The fact that I repeat one sentence or another does not mean that that is more important.

Even if you disagree with some of the rules of law or don't understand the reasons for them, you are bound to follow them as jurors in this case. This is a fundamental part of our system of government by law rather than by the individual views of me as the judge or by you, jurors, who have the responsibility for deciding a specific case.

To the extent I say something differently from the

attorneys, again, these instructions of law govern. Also, I'm not a judge of the facts. I have no opinion as to the appropriate outcome of the case, and you must disregard any facial expressions or questions that I may have asked as far as any way you think I'm indicating how I think this case should come out. It is your memory of the evidence that controls, not my memory, not the attorneys' memory, and you're the ones who render the unanimous verdict.

What is your job as the jury? You're the sole and exclusive judges of the facts. You decide the weight, effect, and value of the evidence. You determine the credibility of the witnesses. Once you determine the facts, it is your duty to apply those facts to the law as I'm explaining it to you. You must determine the facts without prejudice, fear, favor, bias, or sympathy. You may not consider any personal feelings you may have about the race, religion, national origin, sex, or age of any of the witnesses who testified during the trial. You must determine the facts solely from a fair consideration of the evidence. If you were to let fear, favor, prejudice, bias, or sympathy enter into your deliberations, there's a great risk that you would not arrive at a true and just verdict.

You are not to decide the case based on what

you

25 may have heard or read outside the courtroom. You cannot

5

1 speculate or guess as to what might or might not have
2 happened. You must confine your deliberations to the
3 evidence and nothing but the evidence.
4 The lawyers at various times and in closing
5 arguments were allowed to comment on the rules of law, but,
6 again, it's my instructions which govern. Also, if they say
7 something about the evidence that differs from your memory,
8 your collective memory controls.
9 Now, what is the burden of proof? Again, plaintiff
10 has the burden of proof to establish its claim by a
11 preponderance of the evidence, p-r-e-p-o-n-d-e-r-a-n-c-e, the
12 weight of the evidence, the preponderance of the evidence.
13 To establish by a preponderance of the evidence means to
14 prove that something is more likely true than not true, more
15 likely true than not true. In other words, a preponderance
16 of the evidence in the case means such evidence, when
17 considered and compared with that opposed to it, has more
18 convincing evidence and produces in your mind the belief that

what is sought to be proved is more likely true than not true.

In determining whether any fact in issue has been proven by a preponderance of the evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have

produced them. The burden of proof has not been carried if, after you have considered all the evidence, you find that you must speculate, guess, or imagine that one or more of the necessary facts is true.

The burden of proof does not, of course, require proof of an absolute certainty. Proof of an absolute certainty is seldom possible in any case. Nor is proof beyond a reasonable doubt or by clear and convincing evidence required. A burden of proof by a more stringent standard applies in criminal cases and in other special circumstances, but in civil cases generally, and in particular as to all the

issues in this case, the standard of defining the burden of proof is preponderance of the evidence.

In applying this standard of preponderance of the evidence, you will find that the plaintiff has succeeded in meeting the burden of proof on an issue of fact if, after consideration of all of the evidence in the case, and on the basis of the evidence, you find that what is sought be to proved on that issue is more likely true than not true.

And I want to remind you about that example or metaphor I gave you at the start of this trial of blindfolded Lady Justice. Plaintiff has the burden of making those scales tip, albeit slightly, in its favor; but if at the end of all the evidence the scales are evenly balanced or balanced against it, plaintiff has not met its burden.

So how do you decide the case? What is evidence? Evidence consists of the sworn testimony of the witnesses. It includes that deposition testimony which you sometimes saw on videotape and sometimes you heard read in, and all exhibits that were received into evidence and will come with

you into the jury room. There are also a number of facts that have been admitted or stipulated. You will receive those on a piece of paper. You heard many of them read to you.

However, the mere number of witnesses or length of the testimony or number of exhibits has no bearing on what weight you give to the evidence or on whether you find that a party's burden of proof has been met. Weight does not mean the amount of the evidence. Weight means your judgment about the credibility and importance of the evidence.

Now, many things happen over the course of a trial that are not evidence, and I want to go through that with you now. Opening statements and closing arguments made by the lawyers are not evidence in the case. Questions which weren't answered or as to which objections were sustained aren't evidence in the case. Also, the function of the lawyers in making their closing arguments is to point out those things that are most significant or most helpful to their side of the case, and in so doing to call your attention to facts or inferences that might otherwise escape

your notice. In the final analysis, however, it is your recollection and interpretation of the evidence that controls in the case.

Also, many times over the course of this trial, as in every case I've ever sat in for the last twenty years, lawyers make objections to evidence or to questions. That's their job. Their job is to object if they think that evidence isn't reliable or not relevant or is otherwise inadmissible. You should never hold it against a lawyer, or the party that the lawyer works for, for making objections. That's their job in doing that. Also, you should not draw any conclusion from any objections or from my rulings on the objection. These only relate to the legal questions that I had to determine and should not influence your thinking.

Again, when I sustained an objection to a question, the witness was not allowed to answer, and you should not guess as to what that answer may have been had I allowed the question to be answered. Also, if I received evidence but told you it was for a limited purpose, or if in the instructions I'm now giving you I tell you that some of the

evidence should be considered only for that purpose, you're bound by that limitation.

As you heard, sometimes I asked a witness a question if I didn't understand something. I actually offered that to you, and none of you did it, but sometimes,

if I thought something wasn't clear, I asked a question. But, again, you shouldn't assume from anything that I asked that I have an opinion concerning the appropriate outcome of the case or the credibility of any witness.

Now, I want to go through the difference between direct and circumstantial evidence again. There are two types of evidence which you may use to determine the facts of this case: There's direct evidence and circumstantial evidence. Direct evidence is where a witness testifies directly about the fact that is to be proved based on what he or she claims to have seen or heard or felt with his or her own senses, and the only question is whether you believe the witness. Circumstantial evidence is different. It's where no witness can testify directly about the fact that is to be

proved, but you are presented with evidence of other facts and then asked to draw reasonable inferences from them about the fact to be proved.

The law allows both types of proof in a civil trial, and while you may rely entirely on circumstantial evidence, any inferences or conclusions which you draw must be reasonable and natural, based on your common sense and experience of life. In a chain of circumstantial evidence, it is not required that each one of your inferences and conclusions be inevitable, but it is required that any inferences be reasonable.

Direct and circumstantial evidence have equal standing in the law. That is, with respect to what weight should be begin to evidence before you, the law makes no distinction between direct and circumstantial. Also, no greater degree of certainty is required of circumstantial evidence. You are to consider all of the evidence in the case and give each item of evidence the weight that you believe it deserves.

Now let me talk about your role in assessing the

credibility of witnesses. As jurors, your function is to evaluate the exhibits that have been introduced and determine the credibility of witnesses' testimony. Credibility, of course, is simply another word for believability. It is your function to determine the believability of the witnesses who testified. You're free to decide that you believe all of what a witness told you, none of what a witness told you, or some of what a witness told you. You're free to do that in accordance with your collective judgment as to the believability of what it was that the witness told you while testifying.

Neither I nor anyone else can tell you all the different ways that you go about making the important judgment about credibility. However, I can suggest some things for you to consider. You should consider the conduct and demeanor of the witness while testifying, the frankness

or lack of frankness that the witness showed while testifying, the reasonableness or unreasonableness of the

witness's testimony, the probability or improbability of that testimony, the opportunity or lack of opportunity that the witness had to see and know the facts about which he or she was testifying, the accuracy of the witness's recollection, the degree of intelligence shown by the witness, the witness's prior conduct for truthfulness, and whether the witness has attempted to fill in gaps in his memory of events with information he obtained after the event.

You may also consider whether the witness has a motive for testifying and the interest or lack of interest that the witness may have in the outcome of the case. You may take into consideration the character and the appearance of the witness at trial and any bias he's shown in his testimony. You should also consider whether the witness made prior inconsistent statements before trial in considering credibility. This list is not exhaustive. Rather, it is a list of factors you can consider.

You've also heard testimony from persons described as experts, so-called expert witness testimony. Persons who, by reason of skill, training, education or experience have become expert in some field may state their opinions on matters in that field and may also state the reasons for

their opinion.

12

Expert testimony should be considered just like any other testimony. You may accept or reject it, and give it as much weight as you think it deserves, considering the witness's education and experience, the soundness of the reasons given for the opinion, the acceptability of the methods used, and all other evidence in the case.

Okay, now, that is what I would call the first portion of the jury charge, and I'm about to move on to the things that are very specific to this case, the middle portion of the charge.

As you know, the plaintiff in this case is DePuy Mitek. Sometimes the parties refer to it as Mitek. That's the plaintiff. The defendants in this case are Arthrex, Inc. and Pearsalls Limited. You have heard evidence regarding both defendants' involvement in the case, but for purposes of your deliberationss, you should treat Arthrex and Pearsalls the same. And you'll see we've done that in the verdict slip, so you need not make distinctions between the two.

Now, what are the claims here? I'm going to give you a little bit of an overview. Plaintiff alleges that the defendants have infringed upon the claims of the '446 patent, which we've also called the Hunter patent, and that's the patent I handed out on the first day of trial. Defendants deny this allegation.

Deciding whether a claim has been infringed is a

two-step process. The first step is to decide the meaning of the patent claim. I've already made this determination and will instruct you as to the meaning of the claim at issue here, and I showed you what that was on the patent. The second step is to decide whether defendants have made, used, sold, offered for sale, or imported within the United States a product covered by Claim 1 of the Hunter '446 patent. You, the jury, must make the determination about whether there's been an infringement, and that's what you're asked on the verdict form.

Now, the following claim terms -- and I'm

once

again referring back to Claim 1 in the patent that I handed out to all of you -- the following claim terms have the following meanings. You'll see in Claim 1 that there is the abbreviation PE. PE includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene. You've sometimes seen that shortened as UHMWPE.

So let me say that again: PE as it is in Claim 1 includes all polymers formed from a repeating ethylene monomer, including ultra high molecular weight polyethylene.

What do we mean by the "basic and novel properties" of the suture described in the Hunter '446 patent? You remember I handed that out to you on the very first day, and I hope you still have a copy of what I said it was so you

don't have to write it down, but I'm going to read it to you right now. The "basic and novel properties" of the suture described in the Hunter '446 patent are: (1) a surgical suture, (2) composed of two dissimilar yarns from the lists

in Claim 1, (3) where at least one yarn from the first set is in direct intertwining contact with a yarn from the second set, (4) so as to improve pliability and handleability without significantly sacrificing the physical properties of the constituent elements of the suture. You have that already in writing.

So to prevail on its claim, what does the plaintiff have to prove? To prevail on its claim, DePuy Mitek must prove by a preponderance of the evidence that defendants have made, used, offered for sale, sold, or imported into the United States the invention defined in Claim 1 of the Hunter patent.

A person can directly infringe a patent without knowing that what he is doing is an infringement of the patent. He may also infringe even though in good faith he believes that what he is doing is not an infringement of any patent.

Also, an accused product may infringe an asserted patent regardless of whether the accused infringer has its own later-issued patent on the accused product. In other words, the fact that Arthrex has a patent covering FiberWire

does not constitute a defense to infringement of plaintiff's Hunter '446 patent.

So now I want to discuss a very unique patent term, which is the term "consisting essentially of." You've seen that a lot and heard a lot about it, "consisting essentially of."

I call your attention to a phrase used in the Hunter '446 patent, "consisting essentially of," which has a very special meaning in patent law. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I've just defined them.

I'll repeat that again. Here, the phrase "consisting essentially of" means that the claim may encompass FiberWire's sutures that include ingredients that are not expressly listed in the claim, provided those ingredients do not materially affect the basic and novel properties of the invention, as I have just defined them to you.

An effect on the basic and novel characteristics of an invention is material -- that's a legal term, "material." You've heard that term too. An effect on the basic and novel characteristics of an invention is material

if the effect is of importance or of consequence to those of ordinary skill in the art.

Let me state it again: An effect on the basic and novel characteristics of an invention is material if the effect is of importance or of consequence to those of ordinary skill in the art.

The only question here before you is the effect of the silicone coating. The only question here is the effect of the silicone coating. You will need to consider the evidence and decide whether the silicone coating on FiberWire has a material effect on the basic and novel properties of the suture.

Again, you will need to consider the evidence and decide whether the silicone coating on the FiberWire suture has a material effect on the basic and novel properties of

the suture.

Mitek claims it does not have a material or important effect, and Arthrex contends that it does have a material or important effect.

To say it another way, the FiberWire sutures do not infringe the claims of the Hunter '446 patent if the coating on the FiberWire sutures materially affects the basic and novel properties of the invention, as I have defined it.

Ultimately, you will have to decide based upon the evidence whether plaintiff has proven that the coating included in the

sutures sold by the defendants does not materially affect the basic and novel properties of the invention as I have just read them.

I'm going to read that paragraph again that started "to put it another way." To put it another way, the FiberWire sutures do not infringe the claims of the Hunter '446 patent if the coating on the FiberWire sutures materially affects the basic and novel properties of the invention, as I have defined it. Ultimately, you will have

to decide based on the evidence you heard whether plaintiff has proven that the coating included on the FiberWire sutures sold by the defendants does not materially affect the basic and novel properties of the invention as I have just read them to you.

What do I mean by materially affecting? In determining whether the coating added to FiberWire materially affects the basic and novel properties of the invention, it does not matter whether you determine that the coating has an improving effect or a worsening effect on those properties. The only thing that matters in your analysis is whether the effect is material or important. Material means important. If you decide that the effect is not material, then you should find that FiberWire infringes. If you decide that the effect is important, then you should find no infringement.

In determining whether the coating added to

FiberWire materially affects the basic and novel properties of the invention, you may consider the '446 patent, or the Hunter patent, concerning the effect of coatings.

Actually, both sides rely on the patent to some extent. However, you must look at all the evidence in deciding the question of whether the coating added to FiberWire materially affects the basic and novel properties of the invention as I just read them to you.

I now move on to what I will call Part III, which is the mechanics of deliberation. The first thing that you should do when you go back into that jury room is to select a foreperson. I used to do that when I was a newer judge. I used to watch who took notes, who seemed to be paying attention and who seemed to be daydreaming, who came on time. But it soon became apparent to me that you all know each other a whole lot better than I would know any of you at this point. So, please, the first thing you do is go in and choose a foreperson.

But the foreperson is not more equal than the rest. You've heard, again, both sides say, "We're content with all the jurors." So all of you serve as equals in that room. Rather, the foreperson has certain obligations to me. First, the foreperson will fill in the verdict form. There will be one official verdict form. The foreperson will fill

it in, sign it, date it, and certify that it's unanimous. It

must be a unanimous verdict. It can't be five-three. I don't ever want to hear running tallies. It's not a majority. It's got to be all of you. And I don't want to know where the splits are or when the splits are. I don't want to know until it's unanimous. So it must be a unanimous verdict. The foreperson will, again, fill in the slip, sign it and date it and certify that it's unanimous. That's the first job.

The second job will be to write me questions. Look, patent law can be hard, and this involves science, and so there may be certain questions that you have about the law that applies in this case. I cannot tell you what the testimony was. You have your notes; I have mine. Again, to put together a transcript of what any witness says will take hours. However, you can ask me legal questions like, "What on earth were you talking about when you said consisting essentially of?" I suggest you go through your notes. I noticed many of you diligently taking it down. I

suggest you
listen to the tape recording. I suggest, hopefully, I'll get
you a charge if you're still deliberating tomorrow, you know,
tomorrow morning. But if you have a question that cannot be
answered by internally and you think it's an important
question, the foreperson should write me a note and ask me to
explain. Some of these are tough concepts.
The third role of the foreperson will be to

announce the verdict in court, but the foreperson will not be
standing alone because, of course, this will be a unanimous
verdict, so you'll hear us say "So say you, madam forelady?
So say you, all members of the jury?" So the foreperson will
announce the verdict, but all of you will remain standing.
Now, at this point I want to discuss for a minute
alternates. This is simple. In a criminal case, I have to
exclude two alternates as a matter of constitutional law.
This is a civil case, so all of you will deliberate, and
there will be no alternates in this case, so you are all
going to be going in for deliberation.

Third, how do you go about deliberating? These are tough cases, and I have to say, these are fabulous lawyers, and in some ways that's made your job a little harder for you because they're such good lawyers and they've presented to you so much. Everyone goes in with some sense of what you think might be the right answer or what you think might not be the right answer. Everyone will have a sense of where they're leaning on a particular issue, but no one should go in there and say, "I know what I'm going to do, and no one's going to change my mind." That's not what deliberation is all about. Deliberation means going in there but a willingness to change your mind if there's a reasonable and principled basis for doing so.

But no one should change her mind because the

weather's absolutely fabulous, which I'm told it is, or because it's time to go back to work or to your family, or enough with sutures. The truth is, it's too important. You've seen how much these people have put into this case. So, please, no one should change their mind just

because the others think otherwise. Make sure that you believe in a principled and reasoned fashion that that's your verdict because, remember, at the end when it's a unanimous verdict, you're standing to support that verdict.

Now, what I'm going to do is, I want to go and ask the lawyers -- we actually spent, I think, the last couple of days on and off discussing this. I've read it, and I want to make sure I didn't misread something. Or sometimes, you know, you write something out, but then when you read it, you're not sure it comes out as clearly, and I just want to make sure that they're okay with this charge as I've given it to you. So you can stand, you can stretch, but please don't listen. So I'm going to let them right now come talk to me for two seconds, and then I'm going to let you go out.

We're pretty close to organizing these exhibits for all of you, we're pretty far along, and so we'll probably bring them right in with you. You can start the deliberation process, but, frankly, if you're exhausted and want to go home and start tomorrow, fair enough. If you think you can just sort of start making some headway, you'll have about

forty-five minutes or so, that's fine with me too. We'll cut it at 5:00 o'clock.

Okay, let me go talk to the lawyers just for a second.

(Side-bar conference.)

THE COURT: At one point I apparently misread and said the "basic and novel properties of the suture" rather than "basic and novel properties of the invention," as I've described it. I said it correctly about nine times out of ten, but I missed it once, and so if you still need that written instruction, we will correct it. But, otherwise, I am going to let you go. You should let Mr. Alba know if you're just too tired and don't want to get going right now, but I suggest, why don't you just get going for half an hour just to organize yourself. We'll bring in the exhibits. And then you may not want to stay all the way to 5:00. It's been a really long day for everybody here. So why don't we stand in recess, and we'll bring in the exhibits in a second.

THE CLERK: All rise for the jury.

(Jury excused.)

Exhibit 10

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

Test Report: # TEST021104

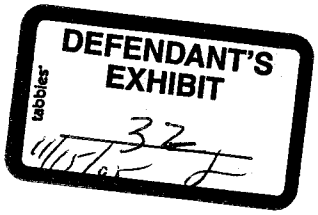
Part number:	Rev:	Description:	Material:
DT PS05 T2	N/A	#2 Fiberwire MED2174 Coated and Uncoated USIPG Dyed	Polyethylene, Polyester
Vendor Name:		Lot Numbers:	Number Tested:
Pearsalls		N/A	3/2
Performed by:		Type of Test:	Date:
Ashley Holloway		Knot Tiedown	02/16/04

Test Objective:

To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture.

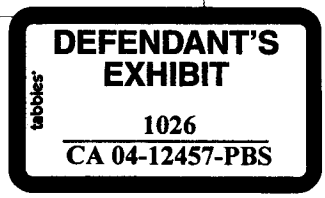
Materials and Methods:

The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture consistently. The loop was then loaded at 12 in/min for 30mm and data was collected at 200 Hz. The peak load required to cause the half hitch to slip was recorded and used for data analysis purposes.



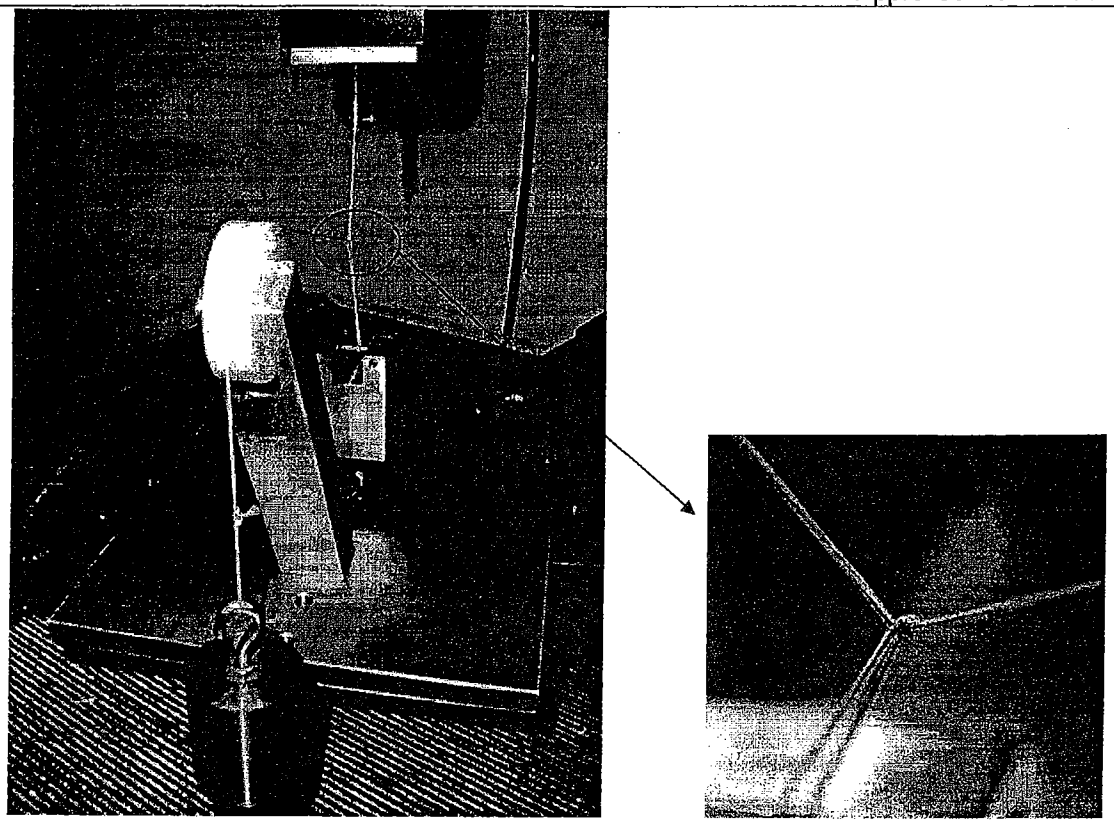
CONFIDENTIAL

ARM 000699



Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310



Data Analysis/Conclusions:

A mean peak force of 12.7 N was recorded for the coated suture. This force represents the force required to initiate slippage of the half hitch. A mean peak force of 32.9 N was recorded for the uncoated suture. A significantly greater amount of force was required to advance the uncoated suture.

CONFIDENTIAL

ARM 000700

2/16/04

Sample ID: coated_uncoated suture_1_021004.mss
Method: Suture Test.msm

Test Date: 2/11/04
Operator: Ashley Holloway

Sample Information:

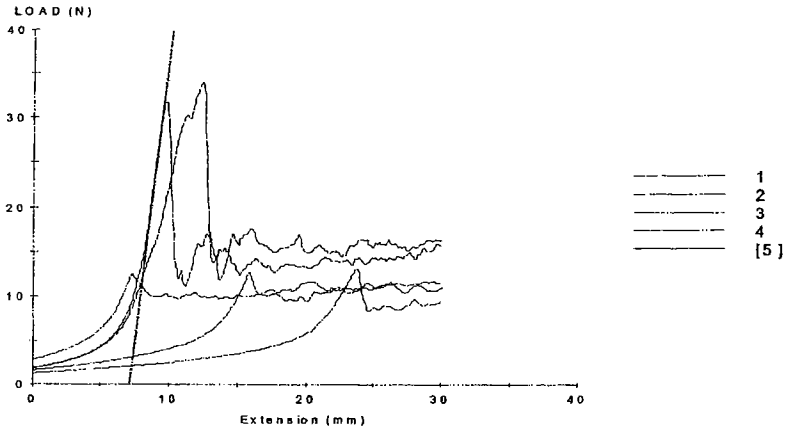
Name	Value
Lot Number	n/a
Part Number	Coated/Uncoated suture test
Revision Level	#2 Fiberwire

Specimen Results:

Specimen #	Peak Load **Coated** (N)		Specimen #	Peak Load **Noncoated** (N)
1	12.43		4	34.04
2	13.08		5	31.71
3	12.64			
Mean	12.72			32.88
Std. Dev.	0.33			1.65
Minimum	12.43			31.71
Maximum	13.08			34.04

Calculation Inputs:
Test Inputs:

Name	Value	Units
Break Threshold	5.620	lbf
Brk Sensitivity	95	%
Data Acq. Rate	200.0	Hz
Ext Limit HI	30.0	mm
Initial Speed	300.00	mm/min
Load Limit HI	150	N
MaxSpecimens	999	
Outer Loop Rate	100	Hz
Slack Pre-Load	5.00	N
Slowdown Extension	0.000	in
Slowdown Load	0.000	lbf
Slowdown Strain	0.000	%
Test Speed	305.00	mm/min



ARM 000701

CONFIDENTIAL

Exhibit 11

Dr. Gitis' Test Results -- Coated vs. Uncoated FiberWire Summary of Test Results

Test	Coated Averages	Uncoated Averages	Difference
Pliability	4.49	7.35	64%
Knot Run-Down	0.22	0.4	81%
Friction	0.09	O.16	77%
Chatter	0.009	0.014	55%
Tissue Drag (Static)	0.91	1.18	30%
Tissue Drag (Dynamic)	0.5	0.78	56%
Knot Slippage (Begin)	3.31	5.14	-55%
Knot Slippage (Untie)	2.52	3.66	-45%

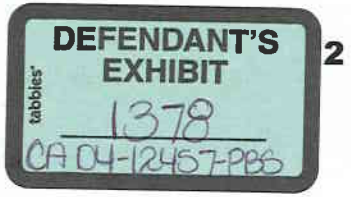


Exhibit 12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

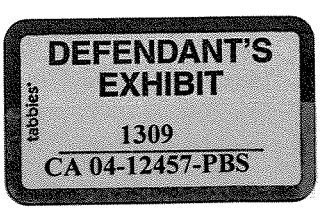
DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

EXPERT REPORT OF ROBERT T. BURKS, M.D.

1. I am an orthopaedic surgeon with the University of Utah Orthopaedic Center. My office is at 590 Wakara Way, Salt Lake City, Utah 84108. I have been practicing for more than 23 years.

2. I received my M.D. from St. Louis University in 1974. I completed a residency in Orthopaedics at the University of California at San Diego in 1983. I completed a knee and sports medicine fellowship at Kaiser Permanente Hospital in San Diego in 1983, and sabbatical at Steadman Hawkins in Vail, Colorado in 1995

3. I am a Professor and Mary Scowcroft Peery Presidential Endowed Chair at the University of Utah Health Sciences Center. I am also the Director of Sports Medicine and Head Physician at the University of Utah. My curriculum vitae are attached as Exhibit 1.



4. My specialties include arthroscopy of the shoulder, knee and ankle, and ligament reconstruction. My research interests include patella stability, cartilage defects, tendon healing to bone.

5. I have reviewed Dr. Fenton's report and I understand he may provide testimony on certain subjects including human anatomy, surgical techniques and surgical devices. I may also provide testimony on these same subjects.

6. I may describe the characteristics of a surgical suture that are generally important to an orthopaedic surgeon. I may also describe the specific features of FiberWire that I find beneficial in my practice.

7. I have been using FiberWire suture in my surgical procedures since 2001. Most of my subjective use of FiberWire occurs during surgery and in the surgical environment, FiberWire is generally wet.

8. Sometime in February 2006, I was contacted by attorneys for Arthrex, Inc. and asked to conduct a tactile feel analysis as well as a knot tie-down analysis of coated and uncoated FiberWire suture. I agreed to conduct the analysis.

9. In March 2006, I received two samples of suture labeled "suture A" and "suture B." Each sample was on a spool and was approximately 3 meters in length. I was told by Arthrex's attorneys that one sample was coated US No. 2 FiberWire and that the other sample was uncoated US No. 2 FiberWire, however, I was not told which sample was coated and which was uncoated.

10. I took the sutures and cut them into some lengths that are appropriate for intraoperative tying and for intraoperative knot tying done arthroscopically. This allowed 5 strands from each spool.

11. I conducted a tactile feel analysis of both suture samples ("suture A" and "suture B"). During the analysis, I noticed that the sample labeled "suture A" generally felt smoother than "suture B." The difference between the two samples was even more pronounced when they were wet, which is how I am most accustomed to using FiberWire.

12. I also conducted a knot tie-down analysis on the two suture samples. I tied several surgeons knots and found that the knots slid easier on the sample labeled "suture A" as compared with the sample labeled "suture B." I felt less friction when sliding the knot on the sample labeled "suture A" as compared with the sample labeled "suture B." Here again, the difference between the two samples was most noticeable when they were wet, as I am accustomed to using FiberWire.

13. After conducting my analysis, I was informed that "suture A" was the coated FiberWire and "suture B" was the uncoated FiberWire.

14. If asked to testify at trial, I may use physical exhibits, as well as other demonstrative exhibits, which have not yet been developed.

15. Within the past four years, I have testified as an expert at deposition in connection with one other case: Philip D. Ceriani, M.D. v. Lonnie Paulos, M.D., and Simon Finger, M.D., et al, Case #: 030906702 (Civil 3rd District Court, Salt Lake City).

16. I am being compensated at a rate of $400 per hour.

Dated: March 24, 2006

Robert T. Burks, M.D.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Expert Report of Robert T. Burks, M.D., was served, via Fedex (Saturday delivery to Ms. Malinoski and regular delivery to Mr. Gleason), along with a courtesy copy of the text of this report (without exhibits), via email, on the following counsel for Plaintiff on the 24th day of March 2006:

Lynn A. Malinoski
Woodcock Washburn, LLP
One Liberty Place, 46th Floor
Philadelphia, PA. 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Telephone: (617) 439-2000
Facsimile: (617) 310-9000

s/Salvatore P. Tamburo

EXHIBIT 1

CURRICULUM VITAE

PERSONAL DATA

Name:	Robert T. Burks, M.D.
Office Address:	University of Utah Orthopaedic Center 590 Wakara Way Salt Lake City, UT 84101 (801) 587-5455 (801) 587-5411 (fax)
Birth Date:	May 12, 1952
Birthplace:	St. Louis, Missouri
Citizenship:	USA
Social Security #:	

EDUCATION

1974	Southern Methodist University	B.A., Chemistry
1978	St. Louis University	M.D.

RESIDENCY (ORTHOPEDICS)

1979-83	University Hospital Medical Center University of California at San Diego

FELLOWSHIP

7/82-1/83	Knee Fellowship and Sports Medicine with Dale M. Daniel, M.D. Kaiser Permanente Hospital San Diego, California

BOARD CERTIFICATION

7/19/85	American Board of Orthopedic Surgery

PROFESSIONAL EXPERIENCE

1983-86	Private Orthopedic Practice Group Orthopedic Associates, Inc. 3009 North Ballas Road, Suite 105 St. Louis, Missouri 63131
1986-88	Assistant Professor Orthopedic Surgery Wayne State University
	Director of Sports Medicine Harper Hospital
1988-95	Assistant Professor Orthopedic Surgery University of Utah
1994-1999	Associate Professor Orthopedic Surgery University of Utah
1999-Present	Professor Orthopedic Surgery University of Utah
1992 – Present	Director University of Utah Red Butte Sports Medicine Center
1988-92	Team Physician University of Utah
1992-Present	Head Team Physician University of Utah
1992	Adjunct Assistant Professor of Bioengineering
5/95-9/95	Sabbatical with Richard Hawkins at Steadman Hawkins Clinic Vail, Colorado
7/2002	Adjunct Professor of Physical Therapy
2003 - Present	Chairman, Metcalf Memorial Meeting

EDITORIAL EXPERIENCE

1993 - Present	Reviewer for Clinical Orthopaedics and Related Research
1993 - Present	Reviewer for The American Journal of Sports Medicine
2001 - Present	Editorial Board Sports Medicine and Arthroscopy Review
2002 - Present	Editorial Board Member of "Techniques in Knee Surgery"

AWARDS

1983	Vernon P. Thompson Award Western Orthopedic Surgery for paper entitled "Anterior Cruciate Graft Preload and Anterior Knee Stability"
1986	Distinguished Service Award, Meramec Community College
1989	Cabaud Award American Orthopedic Society for Sports Medicine for paper "Biomechanical and Histological Observations on the Dog Patellar Tendon After Removal of Its Central One-Third"
June1999	Outstanding Service Award – AOSSM
June 2000	Selected Outstanding Teacher of the Year Department of Orthopedics
2002	Outstanding Service Award - AOSSM
February 2003	"Anatomic Lateral Ligamentous Reconstruction of the Ankle Utilizing Autologous Hamstring Graft". Curtin MJ, Burks RT, and Melhart K. AAOS, New Orleans 2/03.

RESEARCH AWARDS (GRANTS)

FMRE funds, Biomechanical and Histological Observations on the Dog Patellar Tendon After Removal of Its Central One-Third Wayne State University, $14,000, 1988

3M, for tissue fixation study, $12,125, 1989

Lifecore as co-investigator on hyaluronic acid study, $88,000, 1989

The American Orthopedic Society for Sports Medicine Society, "Biomechanical and Histological Observations on the Dog Patellar Tendon After Removal of Its Medial One-Third," $15,000, 1990

Orthopedic Research and Education Fund, "Biomechanical and Histological Observations on the Dog Patellar Tendon After Removal of Its Medial One-Third," $15,000, 1990

The American Orthopedic Society for Sports Medicine, co-investigator, "The Influence of Interface Area and Interference Fit on the Ultimate Tensile Strength of a Healed Tendon-Bone Tunnel Complex," $15,000, 1998

Evaluation of a single osteochondral autograft plug and the treatment of a large osteochondral lesion in the femoral condyle: Experimental study in sheep. Arthrex $50,000 2002.

SCHOLASTIC HONORS

1982 Outstanding Pediatric Orthopedic Resident

1983 McCoy Award for Most Outstanding Senior Resident

1992 American Orthopedic Society for Sports Medicine - European Society for Surgery of the Knee and Arthroscopy European Traveling Fellow

1997 Elected to Herodicus Society

2001 Mary Scowcroft Peery Presidential Endowed Chair

2001 Elected to American Orthopedic Association

ADMINISTRATIVE EXPERIENCE

1992-2002	Co-Chairman Metcalf Memorial Meeting
2003-Present	Chairman Metcalf Memorial Meeting
2003-Present	Chairman Membership Committee American Orthopedic Society for Sports Medicine
1989-96	Coordinator Orthopedic Mortality and Morbidity Conference
1990-Present	Director Dunbar Sports Medicine Lecture Series
1991-Present	University of Utah Sports Medicine Fellowship Program Director
1998-99	Faculty Council Representative
1998-	American Orthopedic Society for Sports Medicine Membership Committee
2001-2003	Chairman American Orthopedic Society for Sports Medicine Fellowship Director Committee
1999-2001	FPO Clinical Affairs Committee
2000-2001	Faculty Practice Steering Committee
2001	Member of the PM&R Search Committee
1998-Present	Medical Director Sports Medicine
2001-Present	Medical Director Madsen Outpatient Surgery Center
2004-Present	Orthopedic Chairman Search Committee
2004-Present	University of Utah School of Medicine PRT Committee

SERVICE

1992-1997	Utah Delegate to The American Orthopedic Society for Sports Medicine
1995-Present	Utah Delegate to Arthroscopy Association of North America
1993 - 1996	Fellowship Committee American Orthopedic Society for Sports Medicine
1996 - 1998	Committee Chairman (Sports Medicine Fellowship Examination)
1998	University of Utah PRT Committee for Clinical Appointments
1998	Salt Lake City Olympic Committee
1998	American Orthopedics Society for Sports Medicine (Membership Committee)
1999	US Figure Skating Medical Coverage
1999	FPO Clinical Affairs Sub Committee
8/99-Present	Sports Medicine Fellowship Director's Committee Chairman

MEDICAL SOCIETY MEMBERSHIPS

American Academy of Orthopedic Surgeons
American Orthopedic Society for Sports Medicine
Arthroscopy Association of North America
Magellan Orthopedic Society -1992
American Orthopedic Association
Herodicus Society
American Orthopedic Association

ELECTRONIC

"Anatomic Lateral Ligamentous Reconstruction of the Ankle Utilizing Autologous Hamstring Graft". Curtin MJ, Burks RT, and Melhart K. AAOS, New Orleans 2/03.

PUBLICATIONS

Burks RT and Sutherland DH: Stress Fractures of the Femoral Shaft in Children: Report of Two Cases and Discussion. J Pediatr Orthop. 4(5):614-616, 1984.

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Daniel DM, Malcolm,L, Stone M, Losse G, Sachs R, and Burks RT: Instrumented Measurement of Anterior Laxity of the Knee. J. Bone and Joint Surg. 67A:720-726, 1985.

Burks RT and Leland R: Determination of Graft Tension Before Fixation in Anterior Cruciate Ligament Reconstruction. Journal of Arthroscopic and Related Surgery. 4(4):260-266, 1988.

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Burks RT and Schaffer J: A Simplified Approach to the Tibial Attachment of the Posterior Cruciate Ligament. CORR 254:216-219, 1990.

Burks RT, Haut RC, and Lancaster RL: Biomechanical and Histological Observations on the Dog Patellar Tendon After Removal of Its Central One-Third. Am. J. Sports Med. 18(2):146-153, 1990.

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Faciszewski T, Burks RT, and Manaster, BJ: Subtle Injuries of the Lisfranc Joint. J. Bone and Joint Surg. 72A:1519-1522, 1990.

Burks RT: Arthroscopy and Degenerative Arthritis of the Knee. A Review of the Literature. Arthroscopy. 6(1):43-47, 1990.

Burks RT: Letter to the Editor. Arthroscopy. 6(1):68-69, 1990.

Burks RT, Bean BG, Marcus R, and Barker HB: Analysis of Athletic Performance with Prophylactic Ankle Devices. Am. J. Sports Med. 19(2):104-107, 1991.

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Burks RT: Practical Considerations in Graft Fixation. Operative Techniques in Orthopaedics, 2(2):71-75, 1992.

Robins AJ, Newman AP, and Burks RT: Post-Operative Return of Motion in Anterior Cruciate Ligament and Medial Collateral Injuries: The Effect of Medial Collateral Ligament Rupture Location. Am. J. Sports Med. 21(1):20-25, 1993.

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Newman AP and Burks RT: Arthroscopic Meniscal Repair: Inside-Out Technique. Operative Tech. Sports Med. 2(3):177-189, 1994.

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Gryler EC, Greis PE, Burks RT, and West J: Axillary Nerve Temperatures During Radiofrequency Capsulorrhaphy of the Shoulder. Arthroscopy 17(6):567-572, 2001.

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Greis PE, Burks RT, Bachus KN, and Luker MG: The Influence of Tunnel Length and Fit on the Strength of a Tendon-Bone Tunnel Complex. Am J Sports Med 29(4):493-497, 2001.

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Burks RT: Letter to the Editor. Arthroscopy 18(5):560, 2002.

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Boylan D, Greis PE, West JR, Bachus KN, and Burks RT: Effects of Initial Graft Tension on Knee Stability After Anterior Cruciate Ligament Reconstruction Using Hamstring Tendons: A Cadaver Study. Arthroscopy 19(7):700-705, 2003.

Lahav A, Burks RT, and Scholl MD: Allograft Reconstruction of the Patellar Tendon: 12-Year Follow-Up. Am J Orthop. 33(12):623-24, 2004.

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BOOK CHAPTERS

Daniel DM, Penner D, and Burks RT: Anterior Cruciate Ligament Graft Isometry and Tensioning. Prosthetic Knee Ligament Reconstruction. Ed. Friedman, M., and Ferkel, R. W.B. Saunders, Philadelphia, 1988.

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Burks RT: American Academy of Orthopaedic Surgeons Monograph Series. Diagnosis of ACL Injuries. Pgs. 19-26. The ACL Deficient Knee. Ed. Edward M. Wojyts. American Academy of Orthopaedic Surgeons, 1994.

Burks RT and Luker MG: Knee Anatomy. Daniel's Knee Injuries: Knee Ligaments and Cartilage Structure, Function, Injury, and Repair. Second Edition. Eds. Robert A. Pedowitz, John O'Connor, and Wayne Akeson. Lippincott Williams & Wilkins, Philadelphia, PA, 2003.

PRESENTATIONS – INTERNATIONAL

"Arthroscopic Ankle Fusion," 52nd Annual Scientific Meeting of Australian Orthopaedic Association, Hobart, Australia, September 1992.

"15 Year Follow-Up of Arthroscopic Meniscectomy," European Society of Sports Traumatology Knee Surgery and Arthroscopy, Berlin, Germany, April, 1994.

"Arthroscopic Ankle Fusion," Dermot Morgan Memorial Scientific Conference, Launceston, Tasmania, June 1993.

"Meniscus Transplantation," Guest Lecturer, Brazilian Orthopedics Society, Belo Horizonte, Brazil, May 1997.

"Rotator Cuff Repair," Guest Lecturer, Brazilian Orthopedics Society, Belo Horizonte, Brazil, May 1997.

"PCL Reconstruction," Guest Lecturer, Brazilian Orthopedics Society, Belo Horizonte, Brazil, May 1997.

"Athletic Shoulder Injuries," Guest Lecturer, Brazilian Orthopedics Society, Belo Horizonte, Brazil, May 1997.

"Arthroscopic Ankle Fusion," Guest Lecturer, Brazilian Orthopedics Society, Belo Horizonte, Brazil, May 1997.

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Revised 10/26/05

Exhibit 13

US006716234B2

(12) **United States Patent**
Grafton et al.

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

(75) Inventors: **R. Donald Grafton**, Naples, FL (US); **D. Lawson Lyon**, Exeter (GB); **Brian Hallet**, Taunton (GB)

(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

(65) **Prior Publication Data**

US 2003/0050666 A1 Mar. 13, 2003

(51) **Int. Cl.**[7] **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

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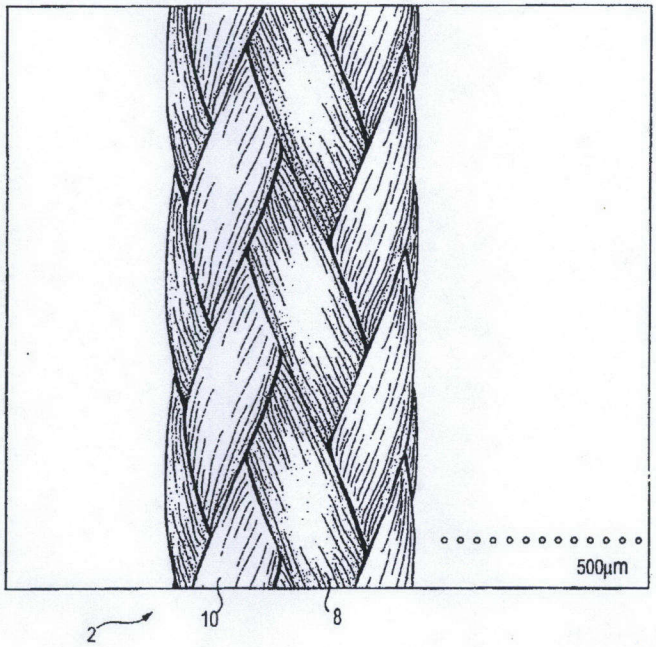
Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Dickstein Shapiro Morin & Oshinsky, LLP

(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



DEFENDANT'S EXHIBIT
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CA 04-12457-PBS

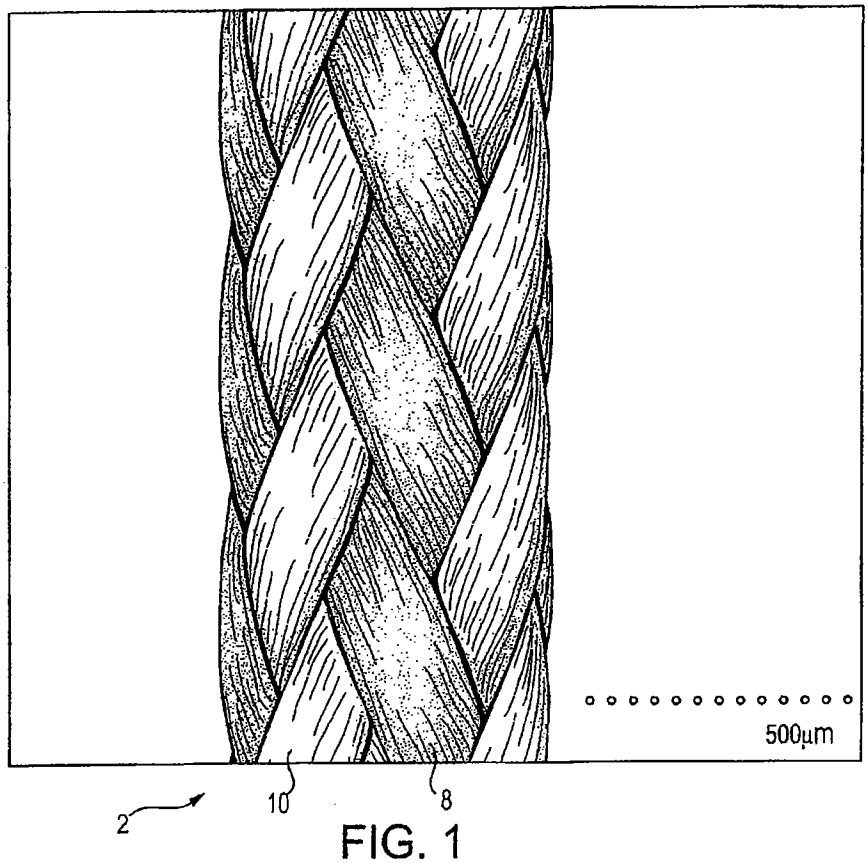

FIG. 1

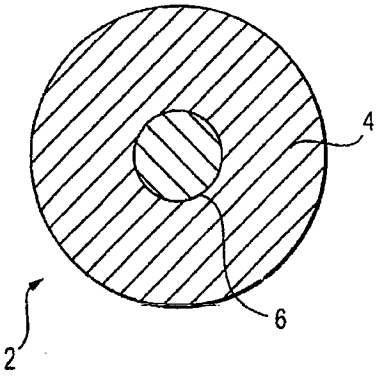

FIG. 2

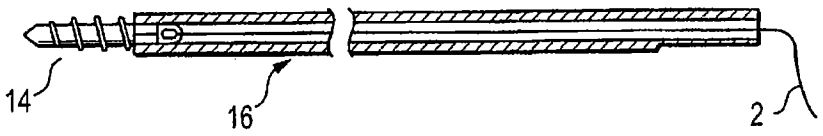

FIG. 3

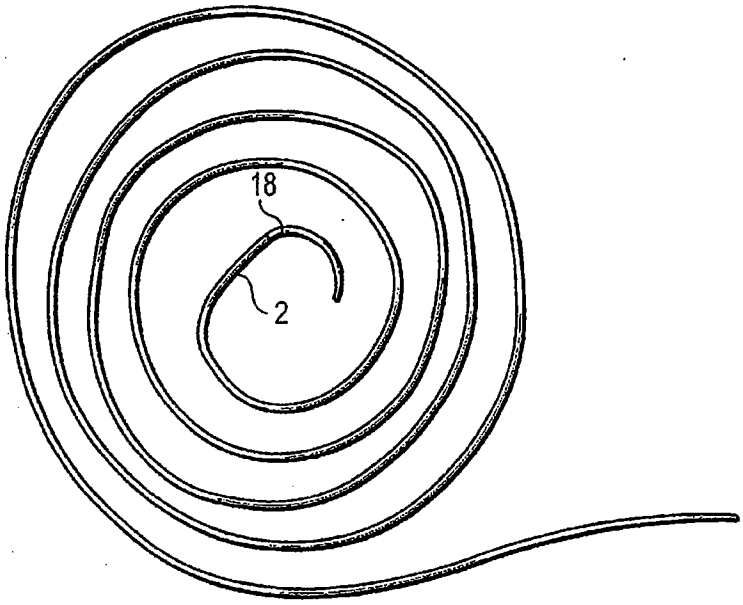

FIG. 4A

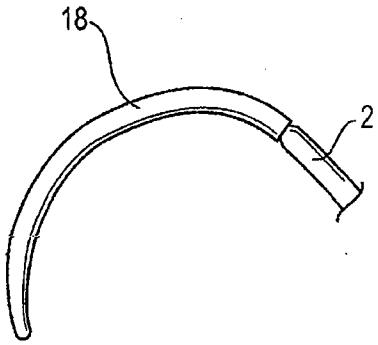

FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. 1 is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. 2 is a schematic cross section of a length of suture according to the present invention.

FIG. 3 is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. 4A and 4B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1, a scanning electron micrograph of a length of suture 2 according to the present invention is shown. Suture 2 is made up of a cover 4 and a core 6 surrounded by the cover. See FIG. 2. Strands of ultrahigh molecular weight polyethylene (UHMWPE) 8, sold under the tradename Dyneema or Spectra, and strands of polyester 10 are braided together to form the cover 4. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

Exhibit 14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePUY MITEK, INC., a Massachusetts Corporation	)	
Plaintiff	)	
-VS-	)	CA No. 04-12457-PBS
	)	Pages 1 - 87
ARTHREX, INC., a Delaware Corporation, et al,	)	
Defendant	)	

MARKMAN HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

DIANNE B. ELDERKIN, ESQ., LYNN A. MALINOSKI, ESQ., and MICHAEL J. BONELLA, ESQ., Woodcock Washburn, One Liberty Place, 47th Floor, Philadelphia, Pennsylvania, 19103, for the Plaintiff.

CHARLES W. SABER, ESQ. and SALVATORE P. TAMBURO, ESQ., Dickstein Shapiro, LLP, 1825 Eye Street, N.W., Washington, D.C., 20006-5403, for the Defendants.

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
September 26, 2006, 2:00 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
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talking about the coatings, right?

MS. ELDERKIN: Right.

THE COURT: And the coatings make it more slippery, maybe.

MS. ELDERKIN: Purportedly, maybe.

THE COURT: Okay, and lubricous. So they essentially enhance the invention.

MS. ELDERKIN: Right.

THE COURT: All right? So originally I had thought "materially affect the novel and basic characteristics" meant somehow change them. You used the word "alter," and one case uses the word "alter," but the case law doesn't consistently use the word "alter." They usually use the word "materially affect."

MS. ELDERKIN: Materially affect, right.

THE COURT: So if it significantly improves on the invention, materially improves on, let's say, the flexibility, would that be improving the novel and basic characteristics?

MS. ELDERKIN: Well, it's obviously so fact-intensive; you know, how much change is there, how much alteration?

THE COURT: But if it's materially improved, you'd say that that fell within this "consisting essentially of," even if it's not a detracting from?

MS. ELDERKIN: It certainly could. And a lot obviously depends on, what are those novel and basic characteristics? Now, Arthrex argues that those characteristics are flexibility, handleability, and not diminishing the strength of the suture. But our position is that that is much too narrow a definition, that the basic and novel characteristics of this invention encompass this concept that I discussed earlier about mechanical blending of the properties of the two discrete sets of yarns.

Now, it may very well be that the effects of those yarns, one enhances pliability and one enhances strength, but the patent specification is not limited to that. The preferred embodiments are talked about in terms of, well, gee in some preferred embodiments, you might take a weak material that's slippery or lubricous and --

THE COURT: Well, is there evidence that just the yarn piece of it, you know, the braiding of the yarn, is novel and basic?

MS. ELDERKIN: That the braiding of the yarn --

THE COURT: In other words, what makes this novel, this invention?

MS. ELDERKIN: Well, I don't mean to be trite, but everything in the claim, which is the concept of a braided construction, two discrete yarns.

THE COURT: So no suture before it ever had that?

Exhibit 15

LEXSEE 1995 US DIST LEXIS 2602

Analysis
As of: Oct 17, 2007

BINNEY & SMITH INC., Plaintiff, v. ROSE ART INDUSTRIES, INC., Defendants.

No. 94 C 6882

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

1995 U.S. Dist. LEXIS 2602

March 2, 1995, Decided
March 3, 1995, DOCKETED

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff patent holder charged that defendant competitor was infringing on its patent by marketing a product that was similar to the patented product. The patent holder requested a preliminary injunction to keep the competitor from making, using, or selling products that contained the asserted infringing product while the action was pending.

OVERVIEW: Plaintiff patent holder charged that defendant competitor was infringing on its patent by marketing a product that was similar to the patented product. The patent holder requested a preliminary injunction to keep the competitor from making, using, or selling products that contained the asserted infringing product while the action was pending. The court denied the request for preliminary injunction and determined that (1) the patent holder had not made a clear or strong showing of likelihood of success on the merits of patent validity, or infringement but rather only a reasonable showing, (2) the patent holder had not demonstrated irreparable injury but only injury that was capable of monetary damages, (3) the hardships did not weigh in favor of the patent holder because its damages could be compensated while those of the competitor for lost marketing start were difficult to calculate, and (4) the public interest in patent protection was equal to the interest in market protection.

OUTCOME: The court denied the request for a preliminary injunction in the action by plaintiff patent holder for patent infringement by defendant competitor because the court determined that the patent holder had failed to demonstrate that it had a reasonable likelihood of success of proving infringement in the action.

CORE TERMS: patent, filler, prior art, infringement, compound, polyvinyl alcohol, microsphere, invention, plastic, preliminary injunction, composition, modeling, dough, likelihood of success, polyvinyl acetate, obviousness, irreparable harm, injunction, consisting, silicon dioxide, patentee, public interest, infringer's, examiner, invalidity, literal, skill, hardship, patented, monetary

LexisNexis(R) Headnotes

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions
Patent Law > Remedies > Equitable Relief > Injunctions

[HN1] Injunctive relief in patent cases is authorized by *35 U.S.C.S. § 283*. Preliminary injunctions protect the right to exclude secured by a patent while the lawsuit is pending to prevent irreparable harm to the patent owner. A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted. Courts have over the years developed a reluctance to resort to preliminary injunctions in patent infringement cases, and have constructed a rather strict standard for the granting of this form of equitable relief.

Civil Procedure > Remedies > Injunctions > Elements > General Overview
Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions
Patent Law > Remedies > Equitable Relief > Injunctions
[HN2] The determination of whether a preliminary injunction should issue turns upon four factors: (1) the movant's reasonable likelihood of success on the merits; (2) the irreparable harm the movant will suffer if preliminary relief is not granted; (3) the balance of hardships tipping in the movant's favor; and (4) the impact of the injunction on the public interest. Each factor must be weighed and assessed against the others and against the form and magnitude of the relief requested. Id. The burden is always on the movant to show entitlement to a preliminary injunction.

Civil Procedure > Remedies > Injunctions > Elements > Likelihood of Success
Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Burdens of Proof
[HN3] The first factor required to be established by a party seeking a preliminary injunction is a reasonable likelihood of success on the merits when the trial court finally adjudicates the dispute. In order to show a reasonable likelihood of success on the merits, the patentee must establish both validity and infringement of the patents.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions
Patent Law > Remedies > Equitable Relief > Injunctions
[HN4] Substantive issues, such as validity and infringement, are not raised for final resolution by motions for preliminary injunction. A denial of a preliminary injunction does not require that noninfringement be clear beyond all question.

Evidence > Procedural Considerations > Burdens of Proof > Clear & Convincing Proof
Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
[HN5] The patent statute, *35 U.S.C.S. § 282*, provides that a patent is presumptively valid and that the burden of establishing invalidity of a patent or any claim is on the party asserting such invalidity. The party asserting invalidity bears the burden of persuasion and must establish by clear and convincing evidence a prima facie case of invalidity before the patent holder will be required to come forward with evidence to the contrary.

Civil Procedure > Remedies > Injunctions > Elements > Likelihood of Success
Evidence > Inferences & Presumptions > Exceptions > Statutory Presumptions
Patent Law > Remedies > Equitable Relief > Injunctions
[HN6] At the preliminary injunction stage, because of the extraordinary nature of the relief, the patentee carries the burden of showing likelihood of success on the merits of the substantive issues relating to validity and enforceability of patent. The statutory presumption is not evidence which can be weighed in determining the likelihood of success on the merits. The statutory presumption of validity does not relieve a patentee who moves for a preliminary injunction in an infringement action from carrying its normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Remedies > Equitable Relief > Injunctions
[HN7] While it is not the patentee's burden to prove validity, the patentee must show that the alleged infringer's defense lacks substantial merit. The court must make an assessment of the persuasiveness of the challenger's evidence presented in support of invalidity.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > General Overview
[HN8] Invalidity for anticipation exists only if all the elements and limitations of the claimed invention are found within one single prior art reference. A patented combination which results in a more facile, economical or efficient unit, or which provides results unachieved by prior art structures, cannot be anticipated piecemeal by a showing that various elements of the invention are old.

Patent Law > Claims & Specifications > Definiteness > Relative Terms
Patent Law > Claims & Specifications > Enablement Requirement > General Overview

[HN9] To be definite, a patent must particularly point out and distinctly claim the invention. *35 U.S.C.S. § 112*. The use of the word "about" does not render a claim indefinite. The mere fact that specific percentage ranges are not used in the patents in suit will not, in itself, render the claims indefinite. Open-ended composition claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. The scope of the claim must be understandable to the ordinary person skilled in the art.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Nonobviousness > Elements & Tests > Ordinary Skill Standard
Patent Law > Nonobviousness > Elements & Tests > Prior Art
[HN10] A patent may be found invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *35 U.S.C.S. § 103*. The question is not whether the invention is obvious now, but whether it would have been obvious when the invention was made.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN11] The ultimate question of obviousness will be one of law based upon underlying facts in four categories. The four factors relevant to the determination of obviousness are: (1) the level of skill in the pertinent art, (2) the scope and content of the prior art, (3) the differences between the prior art and the claims at issue, and (4) as a guard against using hindsight, the court secondarily considers objective indicia of nonobviousness such as: commercial success, long felt but unsolved need, failure of others, and copying of the invention. Another indicia of obviousness is whether the development achieved unexpected results. In determining obviousness, one must consider the invention as a whole; small differences between the claims and the prior art can therefore give rise to patentability.

Patent Law > Infringement Actions > Claim Interpretation > General Overview
[HN12] The determination of the scope of the claims is a matter of law.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Nonobviousness > Evidence & Procedure > General Overview
[HN13] Obviousness under *35 U.S.C.S. § 103* turns on whether the prior art, including the knowledge available to one of ordinary skill in the art, provides some suggestion or motivation to combine the known elements. The suggestion or motivation to combine references need not be explicit. The knowledge pertaining to the art, including an understanding of the principles and application of the prior art elements of the claimed invention, may lead a person of ordinary skill to combine the relevant teachings. The motivation to combine can arise from the knowledge that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose.

Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations
[HN14] The secondary factors, commercial success, long felt but unsolved need, failure of others, copying of the invention, and unexpected results, are particularly appropriate when trying to determine the obviousness of an invention that combines conventional elements in a new way. When the differences appear technologically minor but nonetheless have a practical impact, particularly in a crowded field, the court must consider the obviousness of the new structure in light of the objective indicia.

Patent Law > Nonobviousness > Elements & Tests > Secondary Considerations
[HN15] Commercial success is most relevant in an obviousness determination when there is evidence of a nexus between commercial success and the merits of the invention.

Patent Law > Infringement Actions > Burdens of Proof
[HN16] The standard of showing infringement at this stage is a reasonable likelihood of success in proving infringement at trial. Determination of infringement involves two steps: (1) construing the claims, which is a question of law; and (2) comparing the properly construed claims with the accused composition to determine whether each limitation of the properly construed claim is found in the accused product.

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN17] In construing the meaning of claims, they must be interpreted in light of the claim language, the specification, and the prosecution history, including prior art, and given the same meaning for the analysis of both validity and infringement.

Patent Law > Claims & Specifications > Claim Language > Claim Transitions

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN18] "Comprising," a patent term of art, is an open transitional word that generally allows additional elements to be added. "Comprising" means "including the following elements but not excluding others." The claims may cover additional elements to the extent of material not disclaimed in distinguishing the prior art. Although an open term, "comprising" cannot extend the scope of the patents to aspects given up during prosecution in distinguishing the invention from the prior art.

Patent Law > Anticipation & Novelty > Combinations

Patent Law > Claims & Specifications > Claim Language > Claim Transitions

Patent Law > Infringement Actions > Claim Interpretation > General Overview

[HN19] The expression "essentially consisting of" is a partially closed transitional phrase. In general, the phrase "essentially consisting of" covers a combination with some additional elements but excludes "additional unspecified ingredients that would affect the basic and novel characteristics of the product defined in the balance of the claim."

Patent Law > Infringement Actions > Claim Interpretation > General Overview

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview

Patent Law > Infringement Actions > Reverse Doctrine of Equivalents

[HN20] The second step in determining infringement is to compare the properly construed claims with the accused composition to determine whether each limitation of the properly construed claim is found in the accused product.

Patent Law > Claims & Specifications > Claim Language > Elements & Limitations

Patent Law > Inequitable Conduct > General Overview

Patent Law > Infringement Actions > General Overview

[HN21] Literal infringement of a claim requires that the allegedly infringing product embody every element and limitation of the claim. To determine whether a claim limitation is met literally, the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for that structure.

Patent Law > Claims & Specifications > Description Requirement > General Overview

[HN22] A patent is not limited to the preferred embodiment shown in the specification.

Patent Law > Infringement Actions > Doctrine of Equivalents > General Overview

Patent Law > Infringement Actions > Reverse Doctrine of Equivalents

[HN23] The reverse doctrine of equivalents is an equitable doctrine invoked in applying properly construed claims to an accused device. Under the reverse doctrine of equivalents an accused article may avoid infringement, even within the literal words of the claims, if it is so far changed in principal from a patented article that it performs the same or a similar function in a substantially different way. The purpose of the "reverse doctrine" is to prevent unwarranted extension of the claims beyond a fair scope of the patented invention. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims.

Patent Law > Infringement Actions > Reverse Doctrine of Equivalents

[HN24] The central question in the reverse doctrine of equivalents is whether the accused product is so far changed in principle that it performs the function of the claimed invention in a substantially different way.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions

Governments > Legislation > Statutory Remedies & Rights

Patent Law > Infringement Actions > Defenses > Marking

[HN25] Irreparable injuries are those that are impossible to measure in monetary terms. While monetary relief is often the sole remedy for past infringement, it does not follow that a money award is also the remedy against future infringement. The patent statute provides injunc-

tive relief to preserve the legal interests of the parties against future infringement that may have marked effects never fully compensable in money. If monetary relief were the sole relief afforded by the patent statute, then injunctions would be unnecessary and infringers could become compulsory licensees during the pendency of the litigation. Because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.

Civil Procedure > Remedies > Injunctions > Elements > Irreparable Harm
Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions
Patent Law > Remedies > Equitable Relief > Injunctions
[HN26] Where a strong or clear showing of validity and infringement has not been made, the moving party must make an independent showing of irreparable harm in order to be entitled to a preliminary injunction.

Civil Procedure > Remedies > Injunctions > Preliminary & Temporary Injunctions
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Remedies > Equitable Relief > Injunctions
[HN27] In patent infringement cases, although there exists a public interest in protecting rights secured by valid patents, the court should focus on whether a critical public interest would be injured by the grant of a preliminary injunction.

COUNSEL: [*1] FOR BINNEY & SMITH, INC., plaintiff: Theodore W. Anderson, Jeffrey Brandon Burgan, Donald Jay Silvert, Leydig, Voit & Mayer, Ltd., Chicago, IL.

FOR ROSE ART INDUSTRIES, INC., defendant: Kathleen Ann Lyons, Keith V. Rockey, Rockey, Rifkin and Ryther, Chicago, IL.

FOR ROSE ART INDUSTRIES, INC., counter-claimant: Kathleen Ann Lyons, Keith V. Rockey, Rockey, Rifkin and Ryther, Chicago, IL.

FOR BINNEY & SMITH, INC., counter-defendant: Theodore W. Anderson, Jeffrey Brandon Burgan, Donald Jay Silvert, Leydig, Voit & Mayer, Ltd., Chicago, IL.

JUDGES: BLANCHE M. MANNING, U.S. District Court Judge

OPINION BY: BLANCHE M. MANNING

OPINION

MEMORANDUM AND ORDER

Plaintiff Binney & Smith, Inc. (Binney & Smith) brought this action against a competitor, Rose Art Industries, Inc. (Rose Art) for alleged patent infringement of *United States Patents Number 5,171,766 ("the '766 Patent")* and Number 5,364,892 ("the '892 Patent"), a continuation in part of the *'766 Patent*. Both patents are entitled "Modeling Dough." The Patents relate to a modeling dough comprising gelled poly(vinyl alcohol), water, and a filler. Binney & Smith moved for a preliminary injunction to prohibit Rose Art from making, using, or selling certain products containing a modeling dough that allegedly infringes the patents in suit. [1] After careful consideration of the evidence, oral arguments, and written submissions of the parties, this Court determines that a grant of injunctive relief is not warranted at this stage of the case.

1 For this motion, the consideration of the claims was limited by Plaintiff to the broadest and next representative claim for each patent, namely:

the *'766 Patent*

Claim 1. A moldable composition comprising poly(vinyl alcohol), water, a gellant, and a filler, said filler consisting essentially of plastic microspheres having a wettable particulate coating.

Claim 2. The composition of claim 1, wherein said wettable particulate coating comprises calcium carbonate.

the '892 Patent

Claim 1. A water-based moldable molding dough composition comprising poly(vinyl alcohol), water, a gellant, and a filler, said composition having a pH of about 7.0 or greater, and said filler consisting essentially of a plastic microspheres.

Claim 2. The composition of claim 1, wherein said plastic microspheres have a wettable particulate coating.

[*2] [HN1]

Injunctive relief in patent cases is authorized by *35 U.S.C. § 283*. Preliminary injunctions protect the right to exclude secured by a patent while the lawsuit is pending to prevent irreparable harm to the patent owner. A pre-

liminary injunction is a drastic and extraordinary remedy that is not to be routinely granted. *Nutrition 21 v. United States, 930 F.2d 867, 869, 18 U.S.P.Q. 2d 1347, 1349 (Fed. Cir. 1991)*; *Illinois Tool Works, Inc. v. Grip-Pak, Inc., 906 F.2d 679, 683, 15 U.S.P.Q. 2d 1307, 1310 (Fed. Cir. 1990)*. Courts "have over the years developed a reluctance to resort to preliminary injunctions in patent infringement cases, and have constructed a rather strict standard for the granting of this form of equitable relief." *Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578 (Fed. Cir. 1983)*.

[HN2] The determination of whether a preliminary injunction should issue turns upon four factors: (1) the movant's reasonable likelihood of success on the merits; (2) the irreparable harm the movant will suffer if preliminary relief [*3] is not granted; (3) the balance of hardships tipping in the movant's favor; and (4) the impact of the injunction on the public interest. *Hybritech Inc. v. Abbott Lab., 849 F.2d 1446, 1451, 7 U.S.P.Q. 2d 1191, 1195 (Fed. Cir. 1988)*; *New England Braiding Co., Inc. v. A.W. Chesterton Co., 970 F.2d 878, 882, 23 U.S.P.Q. 2d 1622, 1625 (Fed. Cir. 1992)*. Each factor must be weighed and assessed against the others and against the form and magnitude of the relief requested. *Id.* The burden is always on the movant to show entitlement to a preliminary injunction. *H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 388, 2 U.S.P.Q. 2d 1926, 1928 (Fed. Cir. 1987)*.

A. Likelihood of Success

[HN3] The first factor required to be established by a party seeking a preliminary injunction is a reasonable likelihood of success on the merits when the trial court finally adjudicates the dispute. *Hybritech, 849 F.2d at 1451, 7 U.S.P.Q. 2d at 1195*. In order to show a reasonable likelihood of success on the merits, the [*4] patentee must establish both validity and infringement of the patents. *Id.*

Deciding whether Binney & Smith has demonstrated a reasonable likelihood of success requires the Court to make factual findings and decide factual issues without all evidence that may be admitted at trial. [HN4] Substantive issues, such as validity and infringement, are not raised for final resolution by motions for preliminary injunction. *Roper Corp. v. Litton Systems, Inc., 757 F.2d 1266, 1271, 225 U.S.P.Q. 345, 348 (Fed. Cir. 1985)*. A denial of a preliminary injunction does not require that noninfringement be clear beyond all question. *Illinois Tool Works, 906 F.2d at 679, 15 U.S.P.Q. 2d at 1307*.

Validity

[HN5] The patent statute, *35 U.S.C. § 282*, provides that a patent is presumptively valid and that the burden of establishing invalidity of a patent or any claim is on the party asserting such invalidity. Generally, the party asserting invalidity bears the burden of persuasion and must establish by clear and convincing evidence a *prima facie* case of invalidity before the patent [*5] holder will be required to come forward with evidence to the contrary. *Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461 (Fed. Cir. 1988)*. [HN6] At the preliminary injunction stage, however, because of the extraordinary nature of the relief, the patentee carries the burden of showing likelihood of success on the merits of the substantive issues relating to validity and enforceability of patent. *Nutrition 21, 930 F.2d at 869, 18 U.S.P.Q. 2d 1347*. The statutory presumption is not evidence which can be weighed in determining the likelihood of success on the merits. *New England Braiding Co., 970 F.2d at 882*. Moreover, the statutory presumption of validity does not relieve a patentee who moves for a preliminary injunction in an infringement action from carrying its normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity. *Id. at 878*.

[HN7] While it is not the patentee's burden to prove validity, the patentee must show that the alleged infringer's [*6] defense lacks substantial merit. *Id. at 883*. The Court must make an assessment of the persuasiveness of the challenger's evidence presented in support of invalidity. *Id.* In the instant case, Rose Art bears the burden of producing evidence sufficient to raise a substantial question regarding the validity of Binney & Smith's two patents. Rose Art challenges the validity of the *'766* and '892 patents by asserting that the patents are anticipated under *35 U.S.C. § 102*, indefinite under *35 U.S.C. § 112*, and obvious under *35 U.S.C. § 103*.

Novelty

[HN8] Invalidity for anticipation exists only if all the elements and limitations of the claimed invention are found within one single prior art reference. *Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir. 1991)*. When the five prior art references produced by Rose Art are compared to the patents in suit, there is no substantial identity to show lack of novelty. No single prior art reference submitted [*7] by Rose Art discloses all the elements of the claimed modeling dough. "A patented combination which results in a more facile, economical or efficient unit, or which provides results unachieved by prior art structures, cannot be anticipated piecemeal by a showing that various elements of the invention are old." *Diamond Rubber Co. v. Consolidated Rubber Tire Co., 220 U.S. 428, 31 S. Ct. 444, 55 L. Ed. 527 (1911)*; *O'Brien v. O'Brien, 202 F.2d 254, 255 (7th Cir. 1953)*. Although the elements in the patents in suit are old, they are combined to produce a new and useful product for

the consumer, therefore, making Binney & Smith's invention novel. Hence, Rose Art's burden of persuasion as to anticipation under *35 U.S.C. § 102* has not been satisfied.

Definiteness

[HN9] To be definite, a patent must "particularly point out and distinctly claim" the invention. *35 U.S.C. § 112*. Generally, the use of the word "about" does not render a claim indefinite. Also, the mere fact that specific percentage ranges are not used in the patents [*8] in suit will not, in itself, render the claims indefinite. Open-ended composition claims are not inherently improper; as for all claims their appropriateness depends on the particular facts of the invention, the disclosure, and the prior art. *Scripps Clinic, 927 F.2d at 1565, 1572, 18 U.S.P.Q. 2d at 1001*. The scope of the claim must be understandable to the ordinary person skilled in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 480 U.S. 947, 107 S. Ct. 1607 (1987)*.

Rose Art also contends that the patents in suit were indefinite and hence, invalid under *35 U.S.C. § 112*. While Rose Art has made general allegations in its counterclaims that the specifications were indefinite, uncertain, not enabling, and failed to set forth the best mode, it has not come forward with evidence regarding any of these assertions in its opposition to the motion for preliminary injunction. Defendant appears no longer to be pressing this argument. The presumption [*9] of validity, therefore, controls at this juncture, and the Court finds no evidence that the patent should be invalid under *35 U.S.C. § 112*.

Obviousness

Rose Art's final ground for seeking invalidity is that the patents in suit are invalid for obviousness under *35 U.S.C. § 103*. [HN10] A patent may be found invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *35 U.S.C. § 103*. The question is not whether the invention is obvious now, but whether it would have been obvious when the invention was made.

[HN11] The ultimate question of obviousness will be one of law based upon underlying facts in four categories. The four factors relevant to the determination of obviousness are: (1) the level of skill in the pertinent art, (2) the scope and content of the prior art, and (3) the differences between the prior art and the claims at issue. *Alco Standard Corp. v. Tennessee Valley Authority, 808 F.2d 1490, 1498 (Fed. Cir. 1986)* [*10] (citing *Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S. Ct. 684, 693-94, 15 L. Ed. 2d 545 (1966)*). Additionally, (4) as a guard against using hindsight, the Court secondarily considers objective indicia of nonobviousness such as: commercial success, long felt but unsolved need, failure of others, and copying of the invention. *Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1569 (Fed. Cir. 1987)*. Another indicia of obviousness is whether the development achieved unexpected results. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1461 (Fed. Cir. 1984)*. In determining obviousness, one must consider the invention as a whole; small differences between the claims and the prior art can therefore give rise to patentability. *See Jones v. Hardy, 727 F.2d 1524, 1529 (Fed. Cir. 1984)*.

The Level of Ordinary Skill in the Pertinent Art

Before reaching the substantive obviousness criteria, the Court must determine the relevant level of art against which obviousness must be measured. In this case, the parties [*11] agree that the appropriate level of ordinary skill in the modeling dough art is held by a chemist having knowledge of chemistry equivalent to a bachelor's degree in chemistry or chemical engineer with a few years experience in polymer chemistry. (Plaintiff's Finding of Fact "FF" 77 & Defendant's Post-Hearing Argument p. 43).

The determination of whether an invention is obvious depends on the opinion of experts based upon their knowledge and experience in that particular art. Two experts, one on each side, purport to speak from the perspective of a person having ordinary skill in this particular art. The experts came to different conclusions on whether the invention was obvious to a person of ordinary skill in this particular art at the time of the invention. Binney & Smith's expert testified that the composition was not obvious. He further testified that it took Rose Art's chief chemist six months to find out what was in the composition, and that the chemist tried many fillers without trying the plastic microspheres of the patents in suit. Rose Art's expert did not sufficiently show that the invention was obvious to overcome the Binney & Smith expert's opinion.

The Scope and Content [*12] *of the Prior Art*

Next, the court must determine the scope and content of the prior art to which a person skilled in the art would use in attempting to improve the subject matter of the claimed invention. The scope and content of the prior art are closely related to the patents in suit. [HN12] The determination of the scope of the claims is a matter of law. *Smithkline Diagnostics Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988)*. The patents in suit are not pioneering and will be given a very limited scope.

The scope and content of the prior art is largely undisputed since most of the prior art that Rose Art put in evidence was considered by the examiner. In support of its obviousness argument, Rose Art offers five prior art references. Three patents, *U.S. Patent 3,135,648* (Hawkins '648), *U.S. Patent 3,607,332* (Wingfield '332) and *U.S. Patent 4,172,054* (Ogawa '054) were considered by the examiner at the Patent and Trademark Office in granting both patents in suit. Another patent *U.S. Patent 4,956,404* (Pelzig '404) is not more material than other prior art; however, it is most like the Rose Art compound. Finally, Rose Art provided a brochure on [*13] Pierce and Stevens DUALITE microspheres, which had the material aspects considered by the examiner.

The Hawkins *'648 Patent* describes a composition containing polyvinyl alcohol, clay (filler), water, and boric acid (gellant). The Hawkins *'648 Patent* teaches all elements of the patents in suit, except the use of plastic microspheres and a pH over about 7.0. The Wingfield *'332 Patent* describes the use of hollow microspheres, but not plastic microspheres. To overcome the prior art, the claim was limited to a filler "consisting essentially of" plastic microspheres having a wettable particulate coating for the *'766 Patent* and essentially of plastic microspheres for the '896 Patent. The partially closed phrase allows the patents in suit to exclude prior art that recites the elements of the claims plus additional elements. This phrase allowed the patents in suit to exclude fillers not materially affecting the characteristics of the compound, and thus, not read on the Hawkins '648 and Wingfield *'332 Patents.*

The Ogawa *'054 Patent* teaches the combination of polyvinyl acetate stabilized with a small amount of polyvinyl alcohol, and the examiner was aware of polyvinyl alcohol-borate gelled systems [*14] during the examination of the *'766 Patent*. During the examination of the *'766 Patent*, the Ogawa *'054 Patent*, in combination with Japanese prior art described a polyvinyl alcohol, borate gel, clay, and water composition. In one of the arguments raised to distinguish the Ogawa *'054 Patent* in light of the Japanese publication, Binney & Smith noted that the prior art suggests using a synthetic latex (the polyvinyl acetate contains usually polyvinyl alcohol as an emulsifying stabilizer. (*'054 Patent*, col. 6 lines 12-13) instead of mere polyvinyl alcohol as the patents in suit claim. Other conventional elements, such as starch bearing material and bread were also distinguished from the patents in suit. Thus, Binney & Smith distinguished a compound that includes a polyvinyl acetate stabilized with a small amount of polyvinyl alcohol from the compound in the patents in suit.

The Pelzig *'404 Patent* also is prior art since it is based on an application filed in January 1989, which is before the date asserted by Binney & Smith. It discloses a compound similar to the Rose Art compound including a polyvinyl acetate emulsion stabilized by polyvinyl alcohol. The Pelzig *'404 Patent* uses about 2.7% [*15] polyvinyl alcohol. (col. 4 lines 18-35). The only significant difference is Rose Art's use of plastic microspheres as the filler. Both parties admit that the Pelzig *'404 Patent* was no more material than other prior art considered by the examiner. It will not render the patent in suit obvious since it is no more material than the Ogawa *'054 Patent*, it covers a different compound, and it does not mention plastic microspheres or a pH level of over 7.0.

The brochure for Pierce and Stevens DUALITE microspheres is not dispositive of obviousness at this stage of the case. The examiner was apprised of the pertinent information during the prosecution of both patents in suit. The examiner knew of and the patents disclose DUALITE by name as a preferred microsphere filler, its ultra-low density characteristics, and its function in the patents in suit as a lightweight filler that reduces the density and occupies volume. The brochure does not suggest the use of plastic microspheres in the molding compound, but lists "specific end uses... cast polymers, body patch, paints, adhesives, sealants, BMC, SMC, rubber compounding, building materials, explosives, paper manufacturing, spackle, polymer concrete." [*16] Rose Art has not defined or related any of these terms to a modeling dough. BMC (Bulk Molding Compound) and SMC (Sheet Molding Compound) are different processes that might not suggest use in a modeling dough for use by children and artists. Certain elements of the modeling dough act like adhesives; however, the DUALITE material does not recommend even for evaluation any specific DUALITE microsphere. Cast polymers may be somewhat similar; however, Rose Art has not shown that the Pierce and Stevens DUALITE brochure suggests combining its teachings with the other prior art to create the patents in suit. It is not presently determinative of obviousness that DUALITE micro spheres were marketed for the express purpose of providing low density fillers since that is how they were portrayed to the reader of the patent.

[HN13] Obviousness under *35 U.S.C. § 103* turns on whether the prior art, including the knowledge available to one of ordinary skill in the art, provides some suggestion or motivation to combine the known elements. *Fromson v. Advance Offset Plate, Inc., 755 F.2d 1549, 1556, 225 U.S.P.Q. 26, 31 (Fed. Cir. 1985).* [*17] The suggestion or motivation to combine references need not be explicit. The knowledge pertaining to the art, including an understanding of the principles and application of the prior art elements of the claimed invention, may lead a person of ordinary skill to combine the relevant teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n. 24, 227 U.S.P.Q. 657, 667 n.*

24 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017, 89 L. Ed. 2d 315, 106 S. Ct. 1201 (1986). The motivation to combine can arise from the knowledge that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. *See Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 878 (Fed. Cir. 1993)*. Thus, the issue of motivation to combine is extremely close in this case.

However, on a motion for preliminary injunction, Binney & Smith must demonstrate the likelihood of success on the merits in light of Rose Art's burden of raising a substantial question regarding the obviousness of the Binney [*18] & Smith's patents. The standard to overcome validity is clear and convincing evidence. The prior art in evidence was before the examiner in the applications for the patents in suit or was analogous to such references and does not provide any new, material information. The burden of persuasion is particularly difficult since Rose Art relies on prior art references no more pertinent than prior art considered by the examiner. Based on the evidence presented, the Court does not find that Rose Art has raised a substantial question of obviousness for either patent in suit.

The Differences Between the Claims in Suit and the Prior Art

The differences between the prior art and the claims for the moldable composition at issue are the use of a filler consisting essentially of plastic microspheres with a wettable particulate coating for the *'766 Patent*, and the use of plastic microspheres and a pH of about 7.0 for the '892 Patent. In distinguishing the prior art from the '892 Patent, Binney & Smith stressed the importance of the pH being over 7.0.

Secondary Considerations

[HN14] The secondary factors, (commercial success, long felt but unsolved need, failure of others, copying of the invention, [*19] and unexpected results) are particularly appropriate when trying to determine the obviousness of an invention that combines conventional elements in a new way. *See Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1273 (Fed. Cir. 1991)* (finding that where the patent at issue is a variation on known themes, the "objective indicia--the so-called secondary considerations-- are most useful to the decision-maker."); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 960 (Fed. Cir. 1986)* (stating that objective evidence "can be the most probative evidence of nonobviousness in the record, and enables the district court to avert the trap of hindsight."). When the differences appear technologically minor but nonetheless have a practical impact, particularly in a crowded field, the Court must consider the obviousness of the new structure in light of the objective indicia. *Continental Can, 948 F.2d at 1273*.

The first factor of commercial success modestly indicates nonobviousness. Binney & Smith's product "Model Magic" has been a commercial success. [HN15] Commercial success is [*20] most relevant when there is "evidence of a nexus between [commercial success] and the merits of the invention." *Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151 (Fed. Cir. 1983)*. Binney & Smith has not shown a strong nexus. Binney & Smith did not firmly establish that "Model Magic" incorporated the subject matter and limitations of the patents in suit. (Russomano, pp. 62-63, 12/22/94). Many factors other than the claimed invention contributed to the success of Binney & Smith's Model Magic, such as the licensing of the "Barney" trademark under which the product was sold. At least some success can be attributable to the patented compound. It is not necessary that the patented invention be solely responsible for the commercial success for this factor to be given weight. *Continental Can, 948 F.2d at 1273*.

The next two factors, long felt but unsolved need and the failure of others, are indicia of nonobviousness. Before the modeling dough disclosed in patents in suit was developed, there had been no lightweight modeling dough available that was water-based, air-drying, free of excessive shrinking, cracking, and crumbling upon drying. [*21] Rose Art's chief chemist could not reproduce the Model Magic compound after working on reverse engineering for six months until he became aware of the plastic microsphere filler through the *'766 Patent*. Based on the above facts, Rose Art's chemists could not readily solve the need that was overcome by the use of a plastic microsphere filler.

The next two factors, copying of the invention and unexpected results, could be an indication of nonobviousness. Rose Art studied the "Model Magic" compound; however, it copied the use of the plastic microspheres. Rose Art did not copy the entire invention. Polyvinyl acetate was included by mistake since Binney & Smith product was misanalyzed, (Plf's FF 79) but the use of polyvinyl acetate was well known at that time. The expected results of a lighter filler by using plastic microspheres now seem obvious using hindsight. However, it has not been shown that results were obvious at the time that the inventions were made.

The evidence on these secondary considerations does not tilt entirely in one direction. However, it supports a finding of nonobviousness. Rose Art has not presented sufficient evidence in the prior art that suggests the desirability [*22] and obviousness of making the modeling dough with plastic microspheres. Although the individual elements of the patents may have been well-

known to those with ordinary skill in the art, Rose Art's evidence does not raise a substantial question of invalidity of the patents in suit at this preliminary stage.

At this point, Binney & Smith has adequately rebutted Rose Art's challenges to the validity of the patents in suit and has shown a reasonable likelihood that Rose Art will fail to carry its burden of invalidity by clear and convincing evidence. However, Binney & Smith has not made a clear or strong showing of likelihood of success on the merits of patent validity, but rather only a reasonable showing.

Infringement

[HN16] The standard of showing infringement at this stage is a reasonable likelihood of success in proving infringement at trial. Determination of infringement involves two steps: (1) construing the claims, which is a question of law; and (2) comparing the properly construed claims with the accused composition to determine whether each limitation of the properly construed claim is found in the accused product. *Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1562 (Fed. Cir. 1990).* [*23]

[HN17] In construing the meaning of claims, they must be interpreted in light of the claim language, the specification, and the prosecution history, including prior art, and given the same meaning for the analysis of both validity and infringement. *Smithkline Diagnostics Inc., 859 F.2d at 882*. Since the claims at issue here have been narrowed to overcome the prior art, the Court will apply the same narrow meaning for determining infringement as it did to find their validity reasonably likely.

In the prosecution history in order to obtain an allowance, Binney & Smith argued to narrow the *'766 Patent* from any filler to a filler "consisting essentially of plastic microspheres having a wettable particulate coating..." and narrowed the filler in the '892 Patent to "a filler consisting essentially of plastic microspheres" in addition to the compound having a pH of about 7.0 or greater.

[HN18] "Comprising," a patent term of art, is an open transitional word that generally allows additional elements to be added to the polyvinyl alcohol, water, gellant, and filler. "Comprising" means --"including the following elements but not excluding others." *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986),* [*24] *cert. denied, 479 U.S. 1030, 107 S. Ct. 875, 93 L. Ed. 2d 829 (1987).* The claims may cover additional elements to the extent of material not disclaimed in distinguishing the prior art. Although an open term, "comprising" cannot extend the scope of the patents to aspects given up during prosecution in distinguishing the invention from the prior art. *See Graham v. John Deere, 383 U.S. at 33*.

[HN19] The expression "essentially consisting of" is a partially closed transitional phrase. In general, the phrase "essentially consisting of" covers a combination with some additional elements but excludes "additional unspecified ingredients that would affect the basic and novel characteristics of the product defined in the balance of the claim." *Water Technologies Corp. v. Calco Ltd., 850 F.2d 660, 7 U.S.P.Q. 2d 1097, 1102 (Fed. Cir. 1988).* Thus, the claims are not limited to plastic microspheres as the only filler as Rose Art contends. The phrase is used in the patents in suit to limit one element (the filler) rather than in the normal [*25] manner as the main transition connecting the preamble with the elements.

Binney & Smith's Proposed Finding of Facts, Conclusions of Law and Argument assert that the addition of other elements must materially affect the functioning or characteristics of the plastic microspheres as a filler. The Court cannot adopt this interpretation of "essentially consisting of" since the additional elements traditionally must affect the larger component, the "product defined by the balance of the claim" or composition, not the elements. Thus, when used on an element, the phrase means that the additional elements must affect basic and novel characteristics of the element (the filler), not merely the subcomponent (the plastic microspheres) to avoid infringement.

Binney & Smith asserts that when the phrase "consisting essentially of" is used with respect to only one element, such as the filler, literal infringement is precluded where that component contains additional filler sufficient to change the basic and novel characteristics of that component. The case cited to support Binney & Smith's contention, *Air Products and Chem., Inc. v. Chas S. Tanner Co., 219 U.S.P.Q. 223, 249 (D.S.C. 1983),* [*26] states that the "essentially consisting of" expression "precludes a finding of literal infringement only where a product contains additional, unrecited ingredients which, in nature and amount, change the basic and novel characteristics of the *product*." (emphasis added). In this particular case, however, the inventive step is primarily the plastic microspheres so the addition of ingredients affecting the filler element would affect the composition as a whole. On these specific facts, the additional ingredient must change the basic and novel characteristics of the entire component or only the filler element to avoid infringement.

The pH Limitation of the '892 Patent

The pH feature was important in overcoming prior art, and the specification clarifies the measure by stating that when the pH is below 7.0, the polyvinyl alcohol

does not gel properly. ('892 Patent, col. 6 line 24). Also, it states that a buffer is needed if pH is below 7.0. (*Id.*, line 34). Finally, the description states that when altering formulas, it is important to maintain a pH near 7.5 or higher. (*Id.*, lines 47-48). Thus, a pH over 7.0 is critical to the function of the disclosed invention. The imprecise [*27] use of a term does not allow the patentee to redefine the term after the issuance of a patent to extend the scope of the patent. A potential infringer in clarifying "about 7.0" could reasonably conclude that a compound with a pH below 7.0 would not infringe. In construing the claim language in light of the specification, the Court determines as a matter of law that "pH of about 7.0 or greater" in claim 1 of the '892 Patent means a pH over 7.0. Thus, the claims of the '892 Patent read on modeling doughs with a pH greater than 7.0.

[HN20] The second step in determining infringement is to compare the properly construed claims with the accused composition to determine whether each limitation of the properly construed claim is found in the accused product. *Hormone Research, 904 F.2d at 1562*. The controversy over the patents in suit centers on five features: (1) literal infringement; (2) the limitation on the filler; (3) the pH level; (4) the relatively low percentage of polyvinyl alcohol used by Rose Art; and (5) the reverse doctrine of equivalents.

Literal Infringement

Rose Art has not admitted literal infringement as Binney & Smith claims. [2] Rose Art admits [*28] that its modeling dough, "Air-Dry Modeling Composition," contains all four elements [3] recited in claims 1 and 2 of both the *'766* and '892 patents. However, [HN21] literal infringement of a claim requires that the allegedly infringing product embody every element and *limitation* of the claim. *Smithkline, 859 F.2d at 889*. To determine whether a claim limitation is met literally, the Court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for that structure. *Pennwalt Corp. v. Durand-Wayland Inc., 833 F.2d 931, 934 (Fed. Cir. 1987)*. Rose Art defends arguing that its compound does not have all the limitations in the patents in suit. Similarly based on the evidence presented, Binney & Smith has not shown that the Rose Art compound contains all the limitations.

2 A note made by Rose Art's Kennedy detailing a conversation with patent attorney is not an admission of literal infringement. The note relayed the patent attorneys opinion that Binney & Smith would probably take legal action, but the odds of succeeding were placed at 20-25%.

[*29]

3 poly(vinyl alcohol), water, a gellant, and a filler including plastic microspheres.

The Filler

The filler is limited in the broadest claims of both patents to a filler "consisting essentially of plastic microspheres...." In light of the Court's construction of "essentially consisting of," the additional ingredients must change the basic and novel characteristics of the entire filler element or of the compound to avoid infringement. First, the Court must determine whether another filler is present. The Court is not persuaded that the Pelzig *'404 Patent*, which calls silicon dioxide an "additional additive," determines that silicon dioxide is not a filler. Under other cited prior art patents, silicon dioxide can be considered a filler.

The Rose Art Air-Dry Modeling Composition contains silicon dioxide in the amount of 2.4% of the total weight of the composition (20% of the filler) and one percent of the volume. Plastic microspheres in the Rose Art compound comprise 11.6% of the total weight.

The filler described in the patents in suit functions to both fill space and lower overall density. [*30] Rose Art's silicon dioxide is not a lightweight filler. The lightweight characteristics of the Binney & Smith invention is listed as an important characteristic in the patents in suit. Also, silicon dioxide has a very large surface area as compared to the plastic microspheres. The large volume of silicon dioxide overcomes the loss of volume (shrinkage) upon drying. Substantial shrinkage upon drying was another shortcoming in the prior art that both the plastic microspheres and silicon dioxide overcame. Binney & Smith has not overcome the assertion that the addition of silicon dioxide is significant in its nature and in the amount (20% of the filler) used by Rose Art. Since the additional filler affects the filler element, it affects the whole invention in this case. The filler is the claimed limitation that makes the *'766 Patent* nonobvious over the prior art. If Rose Art merely added silicon dioxide just to get around the patent, the addition might not be enough. Since the *'766 Patent* is so narrow, Rose Art may have circumvented the *'766 Patent* by using another filler in addition to the other following distinctions that further support the lack of success in finding infringement. [*31] Binney & Smith has not shown that the addition of silicon dioxide as a filler does not materially affect the basic and novel characteristics of the filler element or the invention as a whole.

The pH Level

As required by the Court's construction of "pH of about 7.0" Binney & Smith has not clearly shown that the pH of the Rose Art compound is over 7.0. A Binney

& Smith declaration [4] filed with its motion determined that the pH (a logarithmic scale) of the Rose Art compound ranged from 6.50 to 6.88, averaging 6.71. In later samples tested by Dr. Olexia after pH level became an issue, Binney & Smith determined that Rose Art's Air-Dry Modeling Compound has a measured pH over 7.0. (Plf's FF 50). The later inconsistent results are not dispositive.

4 Kaufman, a Binney & Smith polymer chemist.

It is not Rose Art's burden to rebut any finding of pH, but Binney & Smith's burden to show that it will prevail. However, Rose Art asserts that a pH over 7.0 is not satisfied by its composition. Rose Art asserts that its composition [*32] does not use polyvinyl alcohol as the primary binder, thus controlling the pH is not necessary for Rose Art to assure gelation. Binney & Smith has not shown otherwise.

Minimal Use of Polyvinyl Alcohol / Reverse Doctrine of Equivalents

Since apparent literal infringement seems conceivable but not presently shown, the Court further considers the equivalents between the patents in suit and the Rose Art compound. As discussed, Binney & Smith, during the prosecution of the patents in suit, distinguished a compound with polyvinyl acetate stabilized with a small amount of polyvinyl alcohol.

Rose Art notes that in the '892 Patent the preferred formulation of the polyvinyl alcohol content was increased from about 8% to about 12% because of a cracking problem. ('892 Patent, col. 3 line 24.) However, [HN22] a patent is not limited to the preferred embodiment shown in the specification. *Ziegler v. Phillips Petroleum Co., 483 F.2d 858, 869, 177 U.S.P.Q. 481 (5th Cir. 1973), cert. denied, 414 U.S. 1079, 38 L. Ed. 2d 485, 94 S. Ct. 597 (1973).* Thus, the minimum disclosed quantity of 4% will [*33] be used in interpreting the claims rather than the 8% or 12% of the preferred embodiments.

The patents in suit disclose about 4% minimum to about 15% polyvinyl alcohol resin. A compound with less than about 4% would not make a suitable molding compound as disclosed by the patents in suit. Binney & Smith did not overcome the Rose Art assertion that its compound contains only about 4.2% polyvinyl alcohol in an analysis most favorable to Binney & Smith (Tsimberg Ex A., para. 6). The Court does not read this as an admission that Rose Art compound contains *at least* 4.2% polyvinyl alcohol. Evidence submitted by Binney & Smith determined the concentration of polyvinyl alcohol in two samples to be 3.6% and 6.08% by weight. (Exhibit 5). If the Rose Art compound only contains 3.6% polyvinyl alcohol, then it would be at the minimum amount of polyvinyl alcohol disclosed in the patents. Binney & Smith has not adequately shown that the Rose Art composition meets the minimal polyvinyl alcohol percentage required by the patents in suit.

An infringing composition must contain enough polyvinyl alcohol to produce the results described in the patent without reading on the distinguished Ogawa '054 [*34] and Pelzig *'404 Patents*. Polyvinyl alcohol in an allegedly infringing compound could not be a mere by-product of using polyvinyl acetate. Commercial polyvinyl acetate emulsions contain a small amount of polyvinyl alcohol (about 2-3%) to stabilize the emulsion, (Def's FF 31) so excluding any use of polyvinyl alcohol would practically cover the use of polyvinyl acetate. However, Binney & Smith alleges Rose Art added an additional 3% polyvinyl alcohol. (Pf's Exhs 11-12). The polyvinyl alcohol portion of the emulsion and the additional 3% still range around 4%.

The patents in suit rely on polyvinyl alcohol as a binder; whereas, Rose Art's polyvinyl alcohol is a secondary binder that stabilizes the polyvinyl acetate, which holds the filler. This mechanism of coalescence is described in the Pelzig *'404 Patent*. The filler could not be added if polyvinyl alcohol was the primary binder since the polyvinyl alcohol would be already solidified. (Def's FF 44) The Rose Art composition is similar to the Pelzig *'404 Patent* except for the plastic microspheres allegedly added after reading the *'766 Patent*.

Rose Art distinguished the Ogawa *'054 Patent* on the ground that it contained a "synthetic latex." [*35] The Rose Art Air-Dry Modeling Compound is over 70% polyvinyl acetate, and uses polyvinyl alcohol as a stabilizer. Thus, a polyvinyl acetate composition that is similar to Rose Art's compound was distinguished from the prior art. It is not proper to narrowly construe claims before the patent examiner to obtain allowance and then broadly before the courts. *See Tandon Corp. v. United States Trade Commission, 831 F.2d 1017, 1021 (Fed. Cir. 1987).*

[HN23] The reverse doctrine of equivalents is an equitable doctrine invoked in applying properly construed claims to an accused device. *Scripps Clinic, 927 F.2d at 1581*. The reverse doctrine of equivalents flows from the Supreme Court's statement that an accused article may avoid infringement, even within the literal words of the claims, if it is so far changed in principal from a patented article that it performs the same or a similar function in a substantially different way. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co., 339 U.S. 605, 608-09, 70 S. Ct. 854, 856, 94 L. Ed. 1097, 85 U.S.P.Q. 328, 330,* [*36] *reh'g denied, 340 U.S. 845, 71 S. Ct. 12, 95 L. Ed. 620 (1950).* The purpose of the "reverse doctrine" is to prevent unwarranted extension of the claims beyond a

fair scope of the patented invention. Application of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims. *Scripps Clinic, 927 F.2d at 1581*.

Rose Art has not made a strong showing that under the equitable doctrine of the reverse doctrine of equivalents, it cannot be found to be an infringer. [HN24] The central question is whether the accused product is so far changed in principle that it performs the function of the claimed invention in a substantially different way. *SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1123-24 (Fed. Cir. 1985)*. There are significant differences between polyvinyl alcohol and polyvinyl acetate, but there are also similarities. Polyvinyl alcohol can be made from polyvinyl acetate by hydrolysis, a chemical reaction. Polyvinyl acetate is not water soluble; whereas, polyvinyl alcohol is water [*37] soluble. (Def's FF 6). The polyvinyl alcohol used by Rose Art gels by cross linking with borate, but the polyvinyl acetate does not react with borate. This gelation (the cross linked polyvinyl alcohol) is a binder, which makes the moldable compound in a similar manner as the patents in suit. However, Rose Art asserts that polyvinyl acetate is its primary binder, but that binder is not as strong as a polyvinyl alcohol sequence.

During the prosecution to distinguish from the prior art, the claims were so restricted in meaning and limited in scope that it appears that the claims might not embrace the modeling dough made or sold by Rose Art. However similar prior art, such as the Pelzig *'404 Patent*, does not include plastic microspheres. To read the patents in suit broadly enough to cover the Rose Art modeling dough, the patents might also read on a mechanism of coalescence distinguished from the patents in suit. (Def's FF 42).

Based on the evidence presented, the plaintiff has not made out a clear and convincing case for infringement. Thus, the Court cannot, on the present record, conclude that Binney & Smith has demonstrated a likelihood of success on the merits.

B. Irreparable Harm

[*38] Next, Binney & Smith must establish that it will suffer irreparable harm if the preliminary injunction is not granted. [HN25] Irreparable injuries are those that are impossible to measure in monetary terms. *Atlas Powder Co. v. Ireco Chem., 773 F.2d 1230, 1233 (Fed. Cir. 1985)*. While monetary relief is often the sole remedy for past infringement, it does not follow that a money award is also the remedy against future infringement. *Id.* The patent statute provides injunctive relief to preserve the legal interests of the parties against future infringement that may have marked effects never fully compensable in money. *Id.* If monetary relief were the sole relief afforded by the patent statute, then injunctions would be unnecessary and infringers could become compulsory licensees during the pendency of the litigation. *Id.* Because the principal value of a patent is its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole. *Hybritech, 849 F.2d at 1459, 7 U.S.P.Q. 2d at 1200*.

In this case, Binney & Smith is not entitled [*39] to a presumption of irreparable harm since it did not clearly show validity and infringement. *See Smith Int'l, 718 F.2d at 1581, 219 U.S.P.Q. at 692*. [HN26] Since a strong or clear showing has not been made, the moving party must make an independent showing of irreparable harm in order to be entitled to a preliminary injunction. *Roper Corp., 757 F.2d at 1271, 225 U.S.P.Q. 349*.

Binney & Smith claims lost investment in its product development and promotion, lost sales opportunities, lost profit margin, and lost shelf space. Loss of sales, profits, and market share is traditionally not irreparable harm. In *Illinois Tool Works*, the Federal Circuit rejected the patentee's argument that potential lost sales alone could demonstrate "manifest irreparable harm" because acceptance of that position would require a finding of irreparable harm to every patentee, regardless of the circumstances. *Id., 906 F.2d at 683, 15 U.S.P.Q. 2d at 1310*. Rose Art's entry into the market with a similar product may have contributed to Binney & Smith's loss of shelf space, may have significantly [*40] damaged Binney & Smith's market exposure and penetration, market share, exclusivity, and sales of its Model Magic. If solely based on the characteristics of the patented product, the substantial loss of business opportunity could be enough to show irreparable harm. However, an unassailable marketing stance of a product will not be protected until the allegedly infringing product has been shown likely to be excludable under Binney & Smith's patent rights. Money damages could effectively compensate Binney & Smith for these alleged injuries.

Injury to patent rights may have irreparable consequences independent of the defendant's ability to compensate in money. *Atlas Powder Co., 773 F.2d at 1233*. The availability of monetary relief is not always an adequate remedy. Because the principal value of a patent is in its statutory right to exclude, the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole. *See Hybritech, 849 F.2d at 1456-57*. Binney & Smith also claims a loss of credibility with key customers that its products were unique and patented. [*41] Confusion over the uniqueness of the product and Binney & Smith's reputation for producing unique products is important as far as it is valid. Binney & Smith must show that any damage to its commercial reputation and good will result from

infringing acts not just from mere competition in order for the Court to enjoin those acts.

Finally, the ability of Rose Art to fully compensate any harm with money damages, will be weighed in determining whether the principles of equity require the granting or denial of a preliminary injunction. In *Illinois Tool Works, 906 F.2d at 679*, the Federal Circuit upheld a denial of a preliminary injunction where the district court considered the alleged infringer's ability to pay sufficient monetary damages for any infringement during the litigation and had concluded there was no irreparable harm. In the record currently before this Court, it appears, from an undisputed affidavit of Rose Art's chief executive officer attesting to Rose Art's financial soundness, that Rose Art can satisfy a monetary damage award if it is eventually found liable for patent infringement. Thus, Binney & Smith's likelihood of suffering [*42] irreparable harm is lessened because Rose Art is a financially responsible company that could satisfy money damages that Binney & Smith might be awarded. *See Nutrition 21, 930 F.2d at 871* (no finding of irreparable harm because alleged infringer is a financially responsible company answerable in damages).

In light of the fact that the Court has concluded that Binney & Smith has not demonstrated that its patent is infringed, the possibility that Binney & Smith might lose profits and goodwill if the Court permits Rose Art to continue to sell its modeling dough is not the type of harm that warrants the issuance of a preliminary injunction. Money damages might not fully compensate Binney & Smith if there were in fact a showing of a likelihood of infringement; however, without a demonstrated likelihood of success on the merits, there is no showing of irreparable harm. Binney & Smith may experience irreparable harm from competition, but the Court should not use an injunction to preclude legitimate competition until there is a determination of infringement and irreparable harm.

C. Balance of Hardships

The third factor in determining whether [*43] to award a preliminary injunction is the balance of the hardships. The Court must balance the harm that will occur to Binney & Smith, the moving party, from the denial of the preliminary injunction with the harm that the non-moving party will incur if the injunction is granted. *See Hybritech, 849 F.2d at 1457*. The Court must weigh "the magnitude of the threatened injury to the patent owner ... in the light of the strength of the showing of the likelihood of success on the merits, against the injury to the accused infringer if the preliminary decision is in error." *H.H. Robertson Co., 820 F.2d at 388, 2 U.S.P.Q. 2d at 1928*.

Preliminary injunction is a drastic remedy, which can cause hardship to both the alleged infringer, if granted, by requiring removal of its product from the market, or to the patentee, if denied, by delaying the exercise of its limited-in-time property right to exclude. *See Illinois Tool Works, 906 F.2d at 683*. Neither hardship necessarily controls in all cases, and a court must balance the hardships in light of all the factors. [*44] *Id.* Since Binney & Smith has not sufficiently persuaded this Court of its reasonable likelihood of success on the merits, and has not established irreparable injury, the balance of hardships will not tip in favor of Binney & Smith though the magnitude of injury could be significant.

The injury to Rose Art would be great if an injunction is issued in error. Rose Art plans to market aggressively its Power Ranger product containing its modeling dough. It cannot quickly change or redevelop another compound and maintain its top-selling toy. Rose Art's license for "Power Rangers" is dependent on the use of the Rose Art modeling compound for which a likelihood of infringement of the patents in suit has not been found. An injunction would also damage Rose Art's reputation and customer relationships. Since Binney & Smith has not shown that the modeling compound used by Rose Art is likely to infringe, forcing the replacement of the Rose Art compound is not warranted at this time. An injunction on the alleged infringement would severely hamper Rose Art's ability to compete. The hardship of preliminarily enjoining Rose Art forcing it to withdraw its product from the market before trial would [*45] be severe. If a preliminary injunction would have a more severe impact on the enjoined party than the moving party would suffer if not granted, that can be a basis for denying the injunction. *Illinois Tool Works, 906 F.2d at 683*. A preliminary injunction would shut defendant out of this market and result in a loss of profits and good will.

Balancing the potential harms to the parties, the Court finds that the potential harm to Rose Art in issuing an injunction would be a greater burden than the potential harm to Binney & Smith if the Court would deny its request for an injunction. The Court thus concludes that the balance of harms weighs in favor of denying Binney & Smith's motion for an injunction on its patent claim.

D. Public Interest

The fourth factor is the impact of a preliminary injunction on the public interest. Rose Art has offered no input on the public interest issue. [HN27] In patent infringement cases, although there exists a public interest in protecting rights secured by valid patents, the court should focus on whether a critical public interest would be injured by the grant of a preliminary injunction. *Hybritech, 849 F.2d at 1458, 7 U.S.P.Q. at 1201*. [*46] The public interest in the toy modeling dough industry is *per*

se not critical. However, patents must be measured against the basic constitutional requirement, "... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *U.S. Const., Art. I, Sec. 8, cl. 8*. The primary purpose is to promote the progress of science by the means of granting exclusive rights as an incentive to create.

The public interest is in improving inventions by building on inventions such that they do not infringe and bypass the technology of the prior inventions. Patents encourage competitors to conduct research, experiment, and attempt to create alternate, improved noninfringing products. Most inventors are creators in part and borrowers in part. Binney & Smith, itself, borrowed the elements of its patents in suit, and combined them in a new way.

Rose Art also borrowed. It did not precisely copy the claimed invention, but learned of using plastic microspheres through the *'766 Patent*. It attempted to improve the invention by designing around it. Rose Art made a major mistake in analyzing the [*47] Model Magic. (Plf's FF 22) Rose Art misidentified the polyvinyl alcohol in Model Magic as polyvinyl acetate and included polyvinyl acetate in their composition. Also, an additional filler was added so that the patents in suit may not literally read on Rose Art's compound. Since Binney & Smith has not shown a reasonable likelihood of success on infringement, it would unduly hinder progress of science by precluding the use of a product before infringement is shown to be likely. This could generate a chilling effect on the development of improved noninfringing compounds.

Generally, the public has an interest in protecting and enforcing valid patents. *Illinois Tool Works, 906 F.2d at 684*; *Hybritech, 849 F.2d at 1458*. The public has a corollary interest in assuring that preliminary injunctions are not improvidently granted where they are not deserved. *H.H. Robertson, Co., 820 F.2d at 391*. A patent should not be enforced beyond its scope. Since Binney & Smith has not made a showing of likelihood of success in proving infringement at trial, Binney & Smith [*48] should not at this point benefit from the general interest in protecting its patent rights. Binney & Smith's right to protect its patent is counterbalanced by Rose Art's right to compete and the public's interest in fostering competition and product availability. *See Illinois Tool Works, 906 F.2d at 684* (approving district court's weighing of public's interest in the protection of patent rights against the alleged infringer's legitimate right to compete "in view of ... [the alleged infringer's] 'remote' showing of likelihood of success in proving infringement at trial."). Although Binney & Smith has shown more than a remote showing of infringement on its narrow patents, the Court finds that at this stage of the litigation, the balance weighs in favor of Rose Art's right to compete legitimately and the public's right to promote the progress of science. Thus, since infringement has not been shown likely, the Court concludes that granting a preliminary injunction based on evidence presented would disserve the public interest.

Conclusion

Giving the most weight to the lack of showing a reasonable likelihood of success of infringement, [*49] the evidence presented in this preliminary injunction motion does not warrant the issuance of an injunction. The next three factors are related to the strength of plaintiff's showing of likelihood of success. Carefully weighing, measuring, and interrelating the four factors and the parties' evidence and arguments on each, this Court determines that Binney & Smith has not sufficiently met its burden of showing that it is entitled to a preliminary injunction. Binney & Smith's motion for preliminary injunction is denied.

ENTER:

BLANCHE M. MANNING

U.S. District Court Judge

DATED: March 2, 1995